

ANNUAL REPORT 2021

Scandinavian Real Heart AB (publ)

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REALHEART

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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.

Ina Laura Perkins Has the Word

2021 was an eventful year for Realheart from start to finish. New CEO, new members of the team, new collaborations, new animal studies, new patents, new listing site - and above all, we took a big step forward when we left the prototype behind us to work entirely with the clinical version of our artificial heart in the future.

At the end of the first quarter, I took over as CEO from the company's founder and innovator Azad Najar. Azad has an incredible energy and a genuine commitment to our artificial heart, and he now has more time for product development, while I have full focus on taking Realheart TAH towards clinical trials and to the market, to all patients waiting for us there.

Today we have a very strong team, thanks to the recruitment of key competencies that we completed during the year. It is difficult to recruit expertise for the niche of medical technology development that we conduct, and I am incredibly proud to have managed to gather knowledge and experience from as many as five other artificial hearts in our project. I dare say that there is no company that knows more than we do in this area today - but no one else is developing the world's first artificial four-chamber heart either.

It was thanks to this combined competence that we were able to identify a way to make our heart up to 20 percent smaller, with all the new opportunities that it is likely to mean in the future. This discovery was made in connection with one of our animal experiments, much thanks to the remote technology that was introduced during the year and which allows our entire team to be involved when the operation is performed. And on site in the operating room, Dilek Gürsoy took over the main responsibility during the past year. She is one of Europe's leading heart surgeons and is passionate about artificial hearts. You can read more about her in an article in this annual report.

The animal studies are carried out as a way of examining that the product works well - and it has done so every time - and to see what improvements can be made in the animal

care protocol, the connection to the animal's anatomy, and in the overall product design. It was after such an operation that we decided to switch to the clinical version in all further work. The clinical version has a much-improved anatomical design, integrated pressure sensors, and the switch implies a smarter use of resources.

When we put 2021 behind us, we have a frozen design of the clinical version. In parallel, work on the clinical control unit - the remote control of the implanted TAH - has begun in collaboration with the experts at Hydrix in Australia. We need a system that is both safe and reliable in the hands of the end user, the patient. One of our pending patents was granted in the US, resulting in protection of our technology concept of four chambers and two pumps in the largest market in the world until 2035.

The rights issue completed in September, provided the company with SEK 54 million (after issue costs) for continued product development and preclinical studies on the way to the first in human trials. In December we took the step from Spotlight Stock Market to Nasdaq First North Growth Market, a larger capital market and internationally more recognized brand, where we can reach a wider range of investors.

We are also very grateful for the €2.5 million grant that we were awarded by the European Innovation Council, EIC. The EIC grant is a hallmark of quality, and it shows that we are on the right track with our research that will be of great importance to the heart pump industry worldwide. The coming year is now about meeting the high expectations that exist from shareholders as well as doctors and patients, and I will do everything in my power for us to reach set milestones.

With several important milestones already reached, I see that we have every opportunity to keep to our overall schedule.

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.

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.

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.

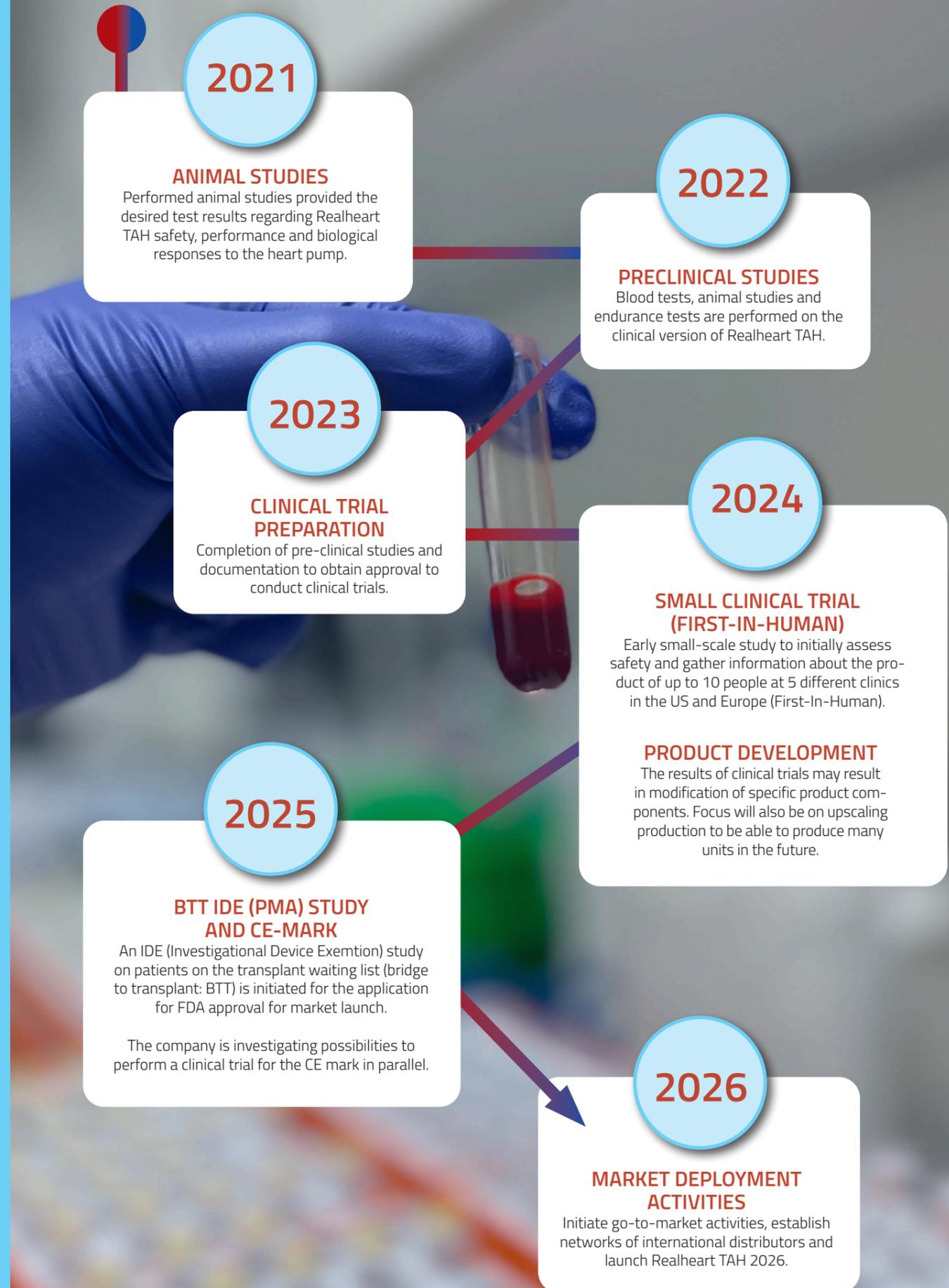
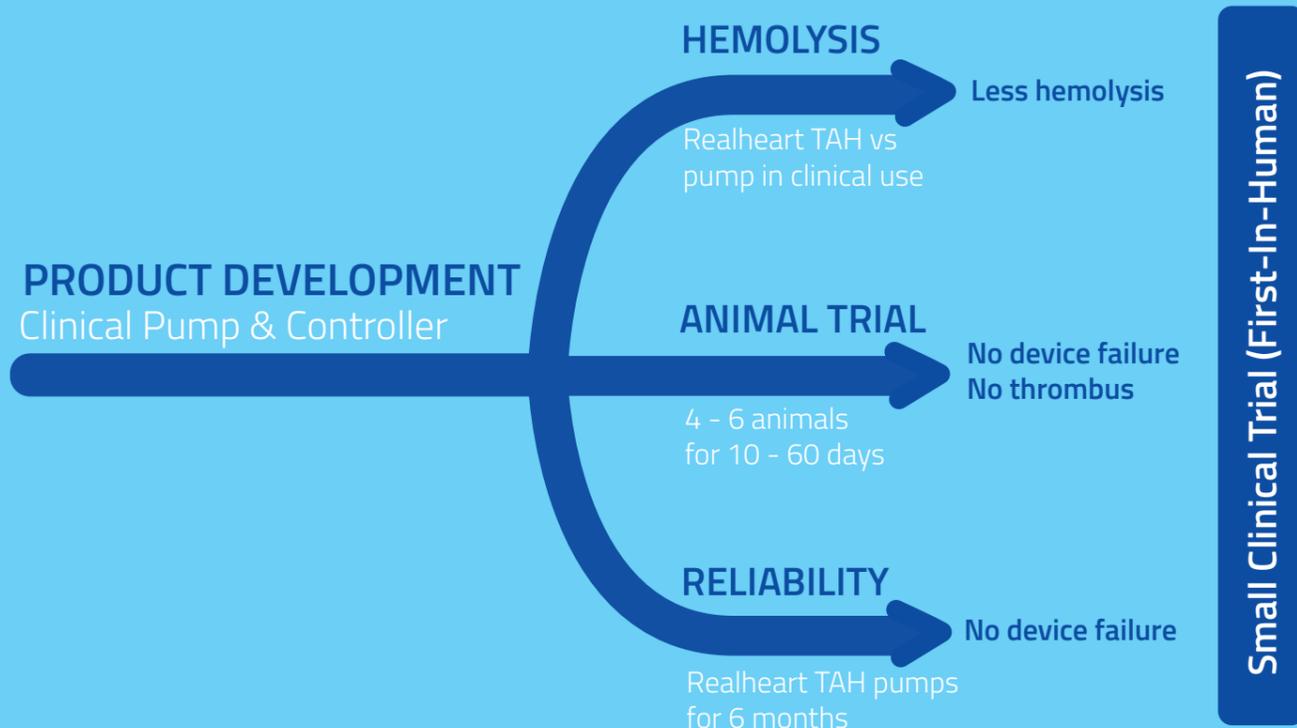
A THIN POWER CABLE

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 long-term trials were due to take place in 2020, but were postponed due to the COVID-19 pandemic. In 2021, the animal studies were resumed remotely with a new surgeon due to travel restrictions and risk groups. During operations in the spring, user errors were identified and were successfully corrected during the autumn. All operations showed that the prototype of the cardiac pump worked as expected. In parallel, the clinical version of the pump was developed -- the one that will eventually be used for patients -- and production was initiated to assemble devices for pre-clinical testing. In 2021, development of the clinical version of the controller started in cooperation with Australian Hydrix Ltd.

The Path Towards Clinical Trials



Dilek Gürsoy - one of Realheart's cardiac surgeons

Dilek Gürsoy

the Surgeon With a Big Heart



When Realheart's artificial heart is tested in animals, Dr. Dilek Gürsoy is the highly experienced surgeon that is standing by the operating table. Dilek's vision is to establish a separate centre for artificial hearts and not just to save patients' lives there – it should also provide the opportunity and freedom to work, exercise, travel, play with children and grandchildren, or whatever provides the patient with a good life quality. A vision she shares with Realheart.

EXISTING HEARTS WITH ANCIENT TECHNOLOGY

Artificial hearts have existed since the 1970s. But they have mainly been used on a temporary basis while waiting for a transplant, and because the equipment is heavy, loud, and has a short battery life. This may not be so strange, however, because the technology has been around for almost 50 years. But since the technology is rarely used, there are few surgeons with experience in its implantation and aftercare.

But Dr. Dilek Gürsoy has the experience. She is known for her research on artificial hearts and her treatment of patients. She has been involved in over 100 artificial heart implantations and performed about 30 on her own.

Dilek Gürsoy was born in Germany in 1976 to parents who immigrated from Turkey. Her career took shape early after her father passed away as a result of heart disease when she was only ten years old. During her first term at medical school, she was already convinced that she had chosen the right specialisation when she became

completely fascinated by a heart operation that she was able to witness, while abdominal surgery did not make a particular impression on her.

She later became the first female surgeon in Europe to implant an artificial heart and has also been awarded Doctor of the Year by the German medical doctor association in 2019. But that isn't something that she attaches great importance to.

"Being first or best at something has never been important to me. What is important to me is that I can sleep well at night and have a good conscience after work. I work in medicine to help patients, and when a patient leaves the clinic healthy and happy, my work is done," says Dilek Gürsoy.

Today Dr Gürsoy works as a consultant at a clinic in Düsseldorf in parallel with her own private practice. She meets heart patients from all over the world. She hopes in the future to establish a centre that is fully focused on treatment with artificial hearts, where she can realize her visions. She often participates in the media to increase awareness of artificial heart therapy.

Photo round image: Simon Earth

W I am sure Realheart will be a good alternative to a transplant, and I will do everything to help drive the development work forward. It's incredibly exciting and a great honour to be involved in shaping the future of medicine.

Dilek Gürsoy

"The standard treatment for a patient with severe heart failure, when all other options have been excluded, is still a heart transplant. But now it is 2022, and it should no longer be the case that one person must die in order for another to live. Artificial hearts are a necessary alternative, but we need better solutions than those that exist today," says Dilek Gürsoy.

She is therefore also active in several research and development projects.

Realheart's artificial heart is next to silent and gives patients a large amount of freedom of movement thanks to its low weight and long battery life. It is also designed to imitate the human heart to reduce the risk of side effects, which was a major problem with the first generation of artificial hearts.

"During all these operations, I have always felt a great humility in the face of the realization that I will most likely save the patient's life - but also change it forever because the patient's quality of life becomes so limited. Some colleagues do not even see an artificial heart as an option. New, innovative products are needed, but also more young, passionate heart surgeons to change that", says Dilek.



Photo center image: Simon Earth
Dilek Gürsoy performs transplants of both donated hearts and artificial ones.

Milestones During the Year

Codialist - Software Expertise

This year, Realheart started a collaboration with Codialist, the medical software expert. The work involves testing and completing the software for the controller prior to initiating the development of the clinical controller. Together with Codialist, Realheart's engineers will perform capacity checks on the software and its automatic algorithm under various simulated clinical scenarios. This is to ensure that the software is error-free at an early stage instead of detecting and correcting them at a later stage, saving both time and resources.

Codialist has accrued many years of clinical and industrial experience. They have unique expertise when it comes to controlling heart pumps and an understanding of the innovation process from idea to market approval. As a result, they quickly developed an understanding of

Realheart's application and the Company's needs right now. They can also complement Realheart's own team during this important development phase and the first steps toward the final clinical controller that is to be used during future clinical trials.

Supplier Agreement - Critical Components

During spring, Realheart entered into a supplier agreement with one of the world's leading medical equipment companies for the critical mechanical valve components for the company's artificial hearts. Realheart's artificial heart (TAH) contains four mechanical valves that mimic the function of the valves of a natural heart. These are critical components in the Realheart system and securing a supplier agreement for them means another step toward the completion of the pump's construction.

“ We are very pleased with all collaborations. The heart valve has a long history of clinical use, and we know that it works in our artificial heart because we have already used it in our tests and animal studies. When it comes to the controller, we benefit a lot from our own team having access to invaluable expertise - which reduces the risk of mistakes and ensures steady progress.

Ina Laura Perkins, CEO at Realheart



Australian Hydrix - Development of the Clinical Controller

Realheart initiated collaboration with Australian Hydrix to develop the clinical controller. The project aim is that the patient should be able to safely and reliably use the controller in their own home after having received Realheart's artificial heart implanted. The importance of a robust user interface is obvious due to the FDA recalls of TAH products, where many recalls are due to problems with the interaction between the user and the device.

The current controller can operate the heart in the way intended for laboratory studies, but in order to use it with patients it must be converted into a product that is user-friendly, safe to use, and in compliance with regulatory requirements. By building Realheart's clinical controller on the Hydrix platform, instead of developing a separate one from scratch, the development time can be significantly reduced.

Hydrix specializes in the development of control systems for heart pumps and artificial hearts and therefore has a great deal of knowledge and experience in the field. Their platform has been used in roughly a dozen such systems and is known for its focus on the needs of the end-user.

Realheart Moves to **Clinical Version** of Its Artificial Heart in Animal Studies

Realheart has decided to switch to the clinical version of its artificial heart – the one that will eventually be used in patients – in further animal studies and all resources are now being devoted to completing this version.

Moving to the 'human version' of Realheart TAH in animal studies is the best use of resources – and a big step forward. During operations carried out in the autumn of 2021, Realheart confirmed that the system works well, and the new surgical team successfully implanted it. Further improvements to the design that were identified are now being implemented, and the focus is now entirely on the clinical version.

The design enhancements also make it possible to further simplify certain aspects of the surgeon's work, which is in line with Realheart's ambition to create the most user-friendly artificial heart on the market.

It is thanks to the enormous, combined expertise that exists within the company today, and experience with five other artificial hearts, that the company has been able to get this far. Work is now moving forward with a version of the artificial heart that is planned to be used in clinical trials – and by making it even easier to use the technology, interest in the product by the medical profession is likely to increase.

Realheart Completed Rights Issue of SEK 61.5 million

At the end of the first half of the year, the Board of Directors of Realheart decided to carry out a new issue of Units consisting of a maximum of 11,279,229 shares and a maximum of 11,279,229 warrants of series 2021/2023: 1, to a maximum of SEK 67.7 million. The condition was approval from an Extraordinary General Meeting in early August. Realheart's shareholders had preferential rights.

At the beginning of August, a prospectus regarding the rights issue was published, which was approved and registered by the Swedish Financial Supervisory Authority. The rights issue took place during the period 16 August to 3 September. A total of 5,802,381 units (91%) were subscribed for and the Company received approximately SEK 61.5 million before deductions for issue costs.

The outcome means that Realheart secured financing to achieve short-term strategic goals including the following milestones:

- Optimization of the heart pump
- Meet product requirements with design work
- Conduct blood tests and flow studies
- Continued animal studies with a focus on long-term functionality

The rights issue means that Realheart's share capital increased by SEK 1,025,000.2 through the issue of 10,250,002 new shares. After registration of the rights issue, Realheart's share capital amounted to SEK 3,280,846.1 divided into 32,808,461 shares

Grant Applications Approved

The Winberg Foundation SEK 500 000

The grant will support further studies of the effects of today's heart pumps on the blood, with the aim of eliminating side effects in the next generation of artificial hearts. The research, conducted jointly by the Karolinska Institutet and the company, will drive development of the entire heart pump industry forward and help Realheart come to market faster

Vinnova MedTech4Health SEK 200 000

The grant, which falls within the scope of skills development for small businesses, will be used for continued blood testing in Realheart's laboratory. The financing is being provided for developing expertise in performing blood tests for pumps in clinical use.

Horizon EIC Accelerator €2.5 million

The European Innovation Council (EIC) was established under the EU's Horizon Europe programme. Its aim is to identify and support cutting-edge new technologies and innovations from early research to international scale-up. The grant enables future EIC investment of €15 million, which is negotiated based on reaching specific milestones in this project.



Realheart Receives **New US Patent** for Its Pump Concept

The company has been granted a patent in the US to protect the concept of four chambers and two pumps until 2035. This patent replaces the previous patent from 2001, which expires shortly. The patent is strategically important because it protects the pump concept in one of the world's largest cardiac pump markets. What sets Realheart TAH apart from other products is its imitation of a natural heart's way of pumping blood around the body. The aim is to minimize the risk of side effects, which are a major problem with heart pump therapy and have hampered the entire artificial heart market.

The patent also protects the idea of using Realheart's concept as a complement to existing heart-lung machines, where they can be improved by moving from continuous blood flow to a pulsating flow, similar to the body's own circulation. This creates opportunities to develop additional spin-off products at a later stage.

10-20 % Smaller Cardiac Pump

During the autumn, the company's design team identified a way to make the heart 10-20 percent smaller in size, which can be of great importance to Realheart's future patients and the market.

Realheart's research and development work is conducted in three parallel work streams: digital (in silico), laboratory (in vitro), and anatomy and animal studies (in vivo). In animal studies during the autumn, the pump was again confirmed to work well. At the same time, the design team who were doing tests in the laboratory found that the newer version of the pump needs a smaller stroke length than the previous one. In addition, the hybrid simulator studies showed that the right pump requires an even smaller stroke than the left one because it works against a lower afterload (pressure in the lungs versus pressure in the aorta). As a result, the clinical version of Realheart TAH will be about 10 percent smaller on the left side and 20 percent smaller on the right side. This is a great example of how Realheart uses different testing strategies to optimise the product development.

There is often a lot of focus on the animal studies, but this is a very good example of the fact that the other parts of research and development work are just as important. A smaller heart also supports the surgeon's work in adapting it to the patient's anatomy, and this is important in terms of the size of the company's potential future market.

Realheart's **Long-Term Studies** in Sheep

Realheart's long-term studies began with a series of operations in sheep. The aim of the study is to gradually increase survival time beyond 24 hours. In the short term the studies will help to identify any product design problems that need to be addressed and cannot be detected by other test methods.

In the longer term, the results from the studies will form the basis for an application for authorisation to initiate clinical trials. Results are reported when all operations have been performed and a consolidated analysis of the data has been performed. The operations are scheduled one by one, in order to provide time for any improvements to the method in between operations. The timetable depends on the time required for these improvements.

University of Bath's Computer Simulations

Getting as close as possible to the way the human heart works – that was the purpose of the computer simulation model that Joseph Bornoff, PhD student at the University of Bath, built and presented at the European Society of Biomechanics in Milan in July 2021.

Joseph Bornoff's model allows a very wide range of operating conditions to be examined to find the pump settings that provide the best energy efficiency and blood handling and then use this information for software programming of the controller. Testing with the same operating conditions in laboratory tests would take an extremely long time and cost a lot of money, thus the computer simulation saves both time and money.

This is very advanced because it involves a valve that is opened and closed, and moves, and is modelled in relation to another valve. What Joseph is doing is really on the cutting edge of simulation research, and it is both important and extremely exciting.

Katharine Fraser's study results Presented in the Journal **Artificial Organs**

Dr. Katharine Fraser is a senior lecture at the Department of Mechanical Engineering at the University of Bath. She works with various types of mechanical support devices for patients with severe heart failure and uses computer simulations and numerical models to study blood damage caused by them. Together with a doctoral student co-funded by Realheart, she has led a research project that aimed at developing a way of using CFD (Computational Fluid Dynamics) to simulate the dynamics that control blood flow in a Realheart TAH. In her published article, she confirms that this method succeeded in achieving good consistency between calculation data and experimental data. The method will be of great importance in the Company's continued efforts to optimise the product, and publication in a trusted scientific journal such as *Artificial Organs* is a great way to strengthen the Realheart brand.



Virtual Patients in Collaboration With **Virtonomy.io**

Realheart is the first user to gain access to Virtonomy's new web platform v-Patients, which includes anatomical 3D models of real heart failure patients. The platform allows Realheart designers to perform virtual implantations on digital replicas of actual humans, in parallel with animal studies. This results in increased efficiency and expertise at the company and helps prepare for clinical trials. The team can meet in a virtual room, and using a standard computer, they can validate a design change in high-precision 3D anatomy models, for example. This capability helps Realheart find the optimal fit for the artificial heart, to treat as many patients as possible, and to identify the right anatomical criteria for patients prior to clinical trials. It is also used in pre-surgical planning for the animal implants.

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.



It is exciting because we are the first to test this new way of working in medical device development. We can experiment in a safe environment, which saves significant resources and reduces the risks compared to conventional methods. Virtonomy has previously helped us adapt our device to the anatomy of humans and large animals, and we look forward to continuing our collaboration as the first users on their platform,

Tomas Finocchiaro
CTO, Realheart

LIST CHANGE

Realheart makes a change from Spotlight to Nasdaq First North Growth Market.

On Friday December 17, Realheart changed its trading location from Spotlight Stock Market to Nasdaq First North Growth Market. The share is traded under the stock symbol #HEART.

Realheart's visibility on Nasdaq First North Growth, which is a trusted, global brand and marketplace, plays an important role when it comes to international expansion and attracting talent and expert partners to the Company. New partnerships and new investors are always kept up to date, and the Company is now looking forward to new successes and opportunities.

This listing was made possible with the help of Skills Corporate Finance and Svensk Kapitalmarknadsgranskning, SKMG.

This is a great opportunity for us as a small research and development company to scale up both parts. The high level of investor interest in Realheart's stock is a key factor in keeping our plans on track and achieving the expected results in the coming years up to market launch.

Ina Laura Perkins
CEO, Realheart



Realheart Team Reinforcement

During the year, Realheart has expanded and strengthened its team by adding the experience and expertise of five other artificial heart projects. The research and development team has been strengthened with engineers with different areas of expertise. A strong team working together toward the same goal is one of the prerequisites for continued development of the product.



Faisal Zaman

R&D Engineer

Master's degree in Biomedical Engineering, Linköping University. Bachelors of Engineering in Biotechnology, BITS Pilani, Dubai.

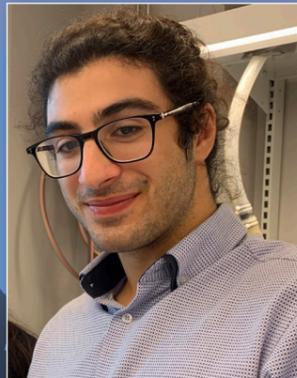
Faisal was previously employed as a Research Engineer in the Unit of Cardiovascular Sciences in Linköping University. His field of expertise is in wet lab testing and medical imaging with a growing expertise in the field of hematology, immunology and fluid mechanics.

"I chose to work at Realheart due to the fact that I always wanted to be a part of novel research. The company, with their vision, brings the perfect scenario to the table for me to grow as a researcher and contribute to the field of science."

Soteris Andreou

R&D Engineer

Soteris studied his bachelors in Cardiff University, where he also worked for 1 year developing medical devices for electrosurgery at Olympus. Soteris comes from Cyprus.



"I'm a quick learner and I'm good at design. Realheart is a great company and developing the artificial heart is an awesome project to be involved with."



Thomas Finocchiaro

Chief Technology Officer (CTO)

Thomas entered the medical device field during his master thesis in electrical engineering. Worked on industry driven ventricular assist device (VAD) projects first and started to work on a TAH at Aachen University (RWTH) during his PhD on the drive system for the ReinHeart TAH. First as Group leader at RWTH, later as CSO of ReinHeart TAH GmbH, responsible for the overall device setup. His skills are Interdisciplinary overview of TAH development (mechanical, electrical and medical) but also finding the best solutions to fulfill the complex requirements.

"Realheart is the perfect fit for my experience from the past 15 years. The company convinced me by the attitude of management and board, that all aspects of bringing the device to the patient are taken care of."



Oliver Chu

Principal Engineer

Bachelor of Science and Master of Science in Mechanical Engineering, Georgia Institute of Technology (USA)

Oliver has 10 years experience in the medical device industry with previous employments at: Alten as a consultant working on projects for Essity and Wellspect, Medeon Bionodesign as a senior engineer, Scandinavian Health Limited as a senior engineer.

He is skilled in medical device development with focuses on mechanical design, design for manufacturing and assembly, design for six sigma, design verification and validation, and process development.

"I chose Realeart for the ambition of developing and commercializing a meaningful product that can save lives and to make this happen by contributing his experience and skills in the medical device field."

Daniel Jonasson

Systems Developer

M.Sc Robotics, Mälardalens Universitet (MDU)

From his previous employment at SAAB Surveillance Daniel has amassed experience in communication filters, both hardware and software, as well as user-interface design and implementation.

He is also skilled in artificial intelligence with experience in image classification and optimization. Daniel also has a great understanding of embedded systems, electronics, FPGA, inverse kinematics and control theory.



"The main reason I joined Realheart was the opportunity to further develop my skills whilst using them for something good. It is best said by the phrase that I associate with all that we do. "No one should die of heart failure."



Helena Stenhem

Brand Manager

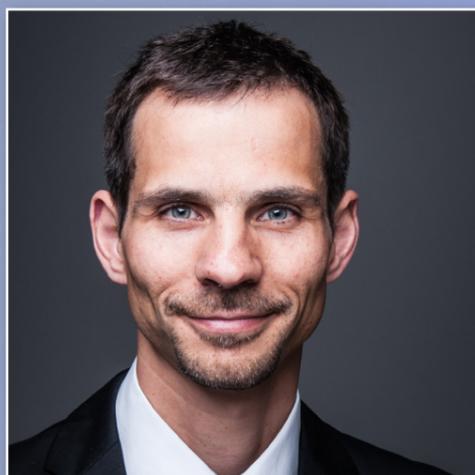
Communicator and project manager in media and communication.

Helena has more than 20 years of experience from innovative environments and dialogue with many different target groups such as researchers, doctors, investors and company managements. Comes most recently from Alfred Nobel Science Park. Responsible for Realheart's brand, marketing and communication through annual reports, announcements, presentations, digital presence, etc.

"Realheart is an incredibly exciting company with enormous potential in the world market. To be a part of the vision: 'No one should die of heart failure', is great."

New **Key Role** at Realheart

Thomas Finocchiaro, Chief Technology Officer



W My first mission is to strengthen the team by both, making best use of everyone's special capabilities and also identifying any filling missing competences.

Thomas Finocchiaro is Realheart's new Chief Technology Officer (CTO). Thomas comes most recently from his role as Chief Scientific Officer (CSO) at Reinheart in Germany. Thomas is an electrical engineer and his PhD research was focused on development of artificial hearts. He also has more than 10 years of experience as head of the Total Artificial Hearts program at Aachen University Hospital.

What do you take with you from your time as CSO at Reinheart?

The overview of how all the different, interdisciplinary requirements engage detailed understanding of past and current artificial heart developments (approaches, problems, solutions). Experience in how to translate needs from the clinician to tasks for engineers. Experience with relevant suppliers and in the cooperation between a contractor and the company.

Why do you think Realheart TAH will be a success?

Realheart will be a success, because the company (the entire team including management board and advisors) has a solid foundation on all relevant topics and not only on technology. It is so easy to neglect fields of expertise.

There is an excellent network, and the team is very dedicated to reaching the goal and helping patients.

The Realheart's feature of including an atria helps to counteract the problem of drainage from the very fragile and collapsible venous system. This is a big challenge for every TAH. It also allows for a design without an additional pneumatic compliance chamber.

The feature of individual pumps also is a big plus when it comes to patient-specific placement of the TAH. Furthermore, it helps to provide a fine-tuned balance between both pumps' output under all possible conditions, a key to success in my experience.

What is your first mission?

To strengthen the team by both making best use of everyone's special capabilities and also identifying and filling missing competence gaps.

Figures and Facts 2021

2037

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.

40

Number of blood tests performed at Karolinska University Hospital in Stockholm each year.

64 million

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

4279

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

4

Number of collaborating academic institutions.

7 000

So few transplants are done 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 2021-01-01 - 2021-12-31.

General Information About the Business

The company is developing an artificial heart that mimics the function of a natural heart, a so-called total artificial heart (TAH). The patented Realheart TAH is developed to mimic the natural human heart's blood flow pattern and function, 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 is patented in many countries and additional patent applications have been filed.

Significant Events During the Financial Year

COVID-19 Pandemic

The pandemic continued in 2021 and has meant restrictions on travel and conferences. Scandinavian Real Heart has continued the development work by using modern technology and working and meeting remotely. The development of the heart pump is proceeding according to plan, but the company has been forced to reschedule some animal studies due to travel restrictions.

During the year, Ina Laura Perkins took over as CEO, replacing Azad Najjar. Azad Najjar continues to play an active role in the company both as a board member and Chief Medical & Innovation Officer. During the year, the company recruited several people with previous experience from similar products. Among other things, Thomas Finocchiaro took over as Chief Technology Officer. This will help to increase the pace of development work.

In December, Scandinavian Real Heart changed listing from Spotlight to Nasdaq First North Growth. This means that the company will have access to a larger capital market in the future.

In connection with the rights issue during the summer, the shareholders were granted warrants, which are also traded on Nasdaq First North Growth. For terms and details, we refer to the company's website.

When it comes to the company's R & D, the costs associated with product development are balanced. In the event that there is general research not linked to product development, it is not balanced.

The work of developing the heart pump for clinical studies in patients is ongoing through pre-clinical studies in animals, research and material development.

In 2021, R&D amounted to SEK 18.8 million or 70% of the cost base before balancing costs.

The Product Development

The work of developing the heart pump for long-term animal tests, establishing new suppliers and partnerships, and to meet the FDA's requirements continues.

Due to the pandemic's impact on e.g. travel restrictions, animal studies have been carried out remotely in Belgium. The work has focused on further development of the automatic control, the mechanical properties of the pump and the clinical product version of both the heart pump and the control unit. At present, we do not see any delay due to changed work on animal studies.

An agreement was concluded with a key supplier of components for the artificial heart. In addition, a collaboration was entered into with Linköping University with a joint doctoral student to visualize the blood flow inside Realheart TAH with the help of magnetic resonance imaging and computer tomography.

The business has been strengthened with six employees, as well as hired labor via partners and consultants.

The goal is still to start clinical studies by 2023.

Regulatory Authorities

In 2021, the company started discussions with a Notified Body that specializes in Class III medical devices to meet EU requirements for clinical trials. The work to meet the US FDA's requirements continues in parallel.

Contribution

SEK 200,000 in financing was received from Vinnova within the strategic innovation program Medtech4health. SEK 500,000 was received from the Winberg Foundation.

Patent Protection

The company has granted patents on the pump principle in the EU, USA, and China. The company has also in recent years filed another series of patent applications. In total, there are eight patent families.

International Publications

During the year, Realheart's collaboration with the University of Bath resulted in a published scientific article in the journal Artificial Organs.

Significant Risks and Uncertainties

The Board estimates that the ongoing Covid-19 pandemic could have a negative effect on the company's results in 2022, but cannot today make an assessment of how large the effects could be. The risks that exist could be delays due to, among other things, travel restrictions and component supply shortage or delayed delivery time. The company works continuously with measures to minimize delays.

Furthermore, the continued product development presupposes that we can continue to solve the financing. The board works continuously 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 first quarter of 2023, but depending on the development, the Company can quickly adjust cost base and activities so that the liquidity is enough over the year of 2023.

To solve the Company's more long-term financing needs, Realheart works continuously to evaluate alternatives for further capitalization of the Company. One future possibility is to finance the Company via equity from financially strong new owners as well as from other non-dilutive sources such as EU support and non-profit foundations.

Financing

In 2021, a rights issue was carried out, which led to the Company gaining access to approximately SEK 54 million after issue costs.

During the year, a grant of EUR 2.5 million was also granted from the EIC (European Innovation Council). This will be paid out in 2022-2024 with the majority in 2022.

The liquidity will primarily be used to ensure the development of the human version of the heart pump in order to reach a level where the company can carry out preclinical studies and preparations for clinical studies.

Ownership

Name	Numbers of shares	Votes	Capital (%)
Najar Medical & Invention AB	3 262 635	3 262 635	9,83
Eskilstunahem Fastighets AB	1 650 006	1 650 006	4,97
Försäkrings AB Avanza	1 589 528	1 589 528	4,79
Nordnet Pensionsförsäkring AB	1 017 440	1 017 440	3,07
Ålandsbanken ABP (Finland) Swedish branch	852 181	852 181	2,57
Formue Nord Marknadsneutral A/S	722 406	722 406	2,18
Najar Bilend	565 823	565 823	1,71
Swedbank Insurance	502 491	502 491	1,51
Forslund Lars	489 474	489 474	1,48
Smartgroup Holding AB	379 336	379 336	1,14
Others	22 152 141	22 152 141	66,75
Total	33 183 461	33 183 461	100,00

Expected Future Development

Realheart's TAH's principle construction is considered to be fully developed. The focus is now on completing the clinical version of both the control unit and the heart pump.

In the coming years, Realheart intends to:

- Conduct preclinical studies.
- Prepare and begin work on clinical studies.
- Conduct parallel discussions with the Notified Body in the EU and with the FDA to ensure the fastest and safest way for the product to market.

Equity

	Share capital	Fund for reserve costs	Share premium forward	Profit brought forward	Profit/loss for the year
At the start of the year (22 558 459 shares)	2 255 846	50 062 104	115 695 766	-87 498 488	-8 820 671
Share issue	1 062 500		49 016 655		
Provision for development fund		18 347 669		-18 347 669	
Transfer of profit/loss for previous year				-8 820 671	8 820 671
Profit/loss for the year					-10 483 500
At the end of the year (33 183 461 shares)	3 318 346	68 409 773	164 712 421	-114 666 828	-10 483 500

Progress of the Company's Operations, Earnings and Position

Amounts in KSEK

	2021-12-31	2020-12-31	2019-12-31	2018-12-31	2017-12-31
Balance sheet total	117 815	78 045	66 614	27 425	33 960
Equity ratio, %	95	92	89	70	81
Cash-to-current liabilities ratio, %	1 032	667	603	111	792
Definitions: see note 9.					

Proposed Appropriation of the Result

Amounts in SEK

The Board of Directors proposes that the capitalised profit be treated so that when carried forward 39 562 093.

Share premium reserve	164 712 421
Loss brought forward	-114 666 828
Loss for the year	-10 483 500
Total	39 562 093

With regard to the results and position in general, reference is made to the following income statement, balance sheet and accompanying notes.

Income Statement

Amounts in SEK

	Note	2021-01-01-2021-12-31	2020-01-01-2020-12-31
Other operating income		541 858	531 474
		541 858	531 474
Operating expenses			
Raw materials and consumables		-913 712	
Purchased services		-10 640 995	-13 302 461
Other external expenses		-12 116 502	-5 916 482
Personnel costs	3	-5 621 541	-3 239 872
Capitalised expenses on own account		18 754 868	13 635 225
Depreciation and impairment of tangible and intangible fixed assets	4	-233 686	-272 835
Other operating expenses		-97 265	-74 767
Operating profit/loss		-10 326 975	-8 639 718
Profit from financial items			
Interest expenses and similar income statement items		-156 525	-180 953
Profit/loss after financial items		-10 483 500	-8 820 671
Profit/loss before tax		-10 483 500	-8 820 671
Profit/loss for the year		-10 483 500	-8 820 671

Balance Sheet

Amounts in SEK

		Amounts in SEK				Amounts in SEK	
	Note	2021-12-31	2020-12-31		Note	2021-12-31	2020-12-31
ASSETS				EQUITY AND LIABILITIES			
Fixed assets				Equity			
<i>Intangible fixed assets</i>				<i>Restricted equity</i>			
Capitalised expenditure on development and similar work	5	68 409 775	50 062 106	Share capital		3 318 346	2 255 846
Concessions, patents, licences, trademarks and similar rights	6	4 993 788	3 799 579	Fund for development expenditure		68 409 773	50 062 104
		73 403 563	53 861 685			71 728 119	52 317 950
<i>Tangible fixed assets</i>				<i>Non-restricted equity</i>			
Equipment, tools, fixtures and fittings	7	90 949	279 099	Share premium reserve		164 712 421	115 695 766
		90 949	279 099	Retained Earnings		-114 666 829	-87 498 488
				Profit/loss for the year		-10 483 500	-8 820 671
						39 562 092	19 376 607
Total fixed assets		73 494 512	54 140 784	Total equity		111 290 211	71 694 557
Current assets				Non-current liabilities			
<i>Current receivables</i>				Other liabilities to credit institutions			
Other receivables		1 337 270	1 157 630		8	2 173 913	2 795 031
Prepaid expenses and accrued income		310 774	291 388			2 173 913	2 795 031
		1 648 044	1 449 018	<i>Current liabilities</i>			
<i>Cash and bank balances</i>		42 672 700	22 455 000	Liabilities to credit institutions		621 118	621 118
Total current assets		44 320 744	23 904 018	Accounts payable		2 209 264	1 488 136
TOTAL ASSETS		117 815 256	78 044 802	Tax liabilities		17 867	57 952
				Other current liabilities		230 628	164 945
				Accrued expenses and deferred income	9	1 272 255	1 223 063
						4 351 132	3 555 214
				TOTAL EQUITY AND LIABILITIES		117 815 256	78 044 802

CASH FLOW STATEMENT

	Amounts in SEK	
Note	2021-01-01- 2021-12-31	2020-01-01- 2020-12-31
Current activities		
Cash flow from operating activities	- 10 483 500	-8 820 671
Adjustments for non-cash items	233 686	272 835
Estimated payroll tax	- 10 249 814	-8 547 836
		-18 759
Cash flow from current operations before changes in working capital	- 10 249 814	-8 566 595
<i>Cash flow from changes in working capital</i>		
Changes in accounts receivable		-
Changes in current receivables	- 199 025	100 097
Changes in accounts payable - trade	721 128	-1 069 302
Changes in current liabilities	74 788	124 625
Cash flow from operating activities	- 9 652 923	-9 411 175
Investing activities		
Investments in intangible fixed assets	- 19 587 414	-14 764 163
Investments in tangible fixed assets		-
Cash flow from investing activities	- 19 587 414	-14 764 163
Financing activities		
New share issue	63 480 012	25 895 509
Issue expenses	- 13 400 857	-4 382 745
Payment of debt	- 621 118	-298 137
Cash flow from financing activities	49 458 037	21 214 627
Cash flow for the year	20 217 700	-2 960 711
Cash and cash equivalents at the start of the year	22 455 000	25 415 711
Cash and cash equivalents at the end of the year	42 672 700	22 455 000

Notes

Note 1 Accounting Principles

Amounts in KSEK 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).

Valuation principles, etc.

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

Public Subsidies

A public subsidy that is not associated with a requirement for future performance is recognised as income when the conditions for obtaining the subsidy have been met. A public subsidy that is associated with a requirement for future performance is recognised as income when such performance has occurred. If subsidies were received before the conditions for recognising them as income were met, they are recognised as a liability.

The item "Other income" includes a public subsidy from Vinnova amounting to SEK 397,000. Scandinavian Realheart has met the requirements associated with these grant payments.

Intangible Fixed Assets

Research and Development Costs

Costs relating to research, i.e. the planned and systematic search with the aim of obtaining new scientific or technical knowledge and insights, are recognised as costs when they arise.

When recognising development costs, the capitalisation model is applied. This means that costs incurred during the development phase are recognised as assets once all the following conditions have been met:

- It is technically possible to complete the intangible fixed asset so it can be used or sold.
- The intention is to complete the intangible fixed asset and use or sell it.
- The prerequisites for use or sale of the intangible fixed asset exist.
- It is likely that the intangible fixed asset will generate future economic benefits.
- There are necessary and adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.

- Expenses attributable to the intangible fixed asset can be reliably calculated.
- Development costs that do not fulfil these criteria for capitalisation are reported when they arise.
- The acquisition value for capitalised costs includes expenditure on the development of the asset. Directly attributable expenses include personnel costs incurred during the course of development work, alongside an appropriate share of indirect costs.

Depreciation of the depreciable amount is done on a straight-line basis over the anticipated useful lifespan. Impairment begins when the asset can be used. The corresponding amount has been transferred to the Fund for development expenditure.

Other intangible fixed assets

Other intangible assets acquired by the company are recognised at their acquisition value minus accumulated depreciation and write-downs.

Patents

Patents acquired by the company are recognised at their acquisition value minus accumulated depreciation and write-downs.

Depreciation

Depreciation takes place on a straight-line basis over the estimated useful life of the asset. The depreciation is expensed in the income statement.

<i>Intangible fixed assets</i>	%
<i>Acquired intangible assets</i>	
Patents	12.50

Tangible Fixed Assets

Tangible fixed assets are recognised at acquisition cost minus accumulated depreciation and impairment. The acquisition value includes both the purchase price and costs that are directly attributable to the acquisition.

Depreciation

Depreciation is carried out on a straight-line basis over the asset's estimated useful life to reflect the expected consumption of the asset's future economic benefits. The depreciation is expensed in the income statement. The estimated residual value has been taken into account, as determined at the point of acquisition.

Evaluation of Impairment Requirements for Tangible and Intangible Fixed Assets

At each balance sheet date, an assessment is made of whether there is any indication that the value of an asset is lower than its carrying amount. If there are any such indications, then the recoverable value of the asset is calculated. If the recoverable value is less than the reported value, an impairment analysis is made and recognised as an expense. An internally developed intangible fixed asset that is not yet ready for use or sale at the balance sheet date is always evaluated for the purposes of impairment. The recoverable value for an asset or cash-generating unit is the highest of its fair value with deductions made for costs of sale and its value in use. The fair value less sale costs consists of the price the company calculates it would obtain upon a sale between knowledgeable parties who are independent of each other, and who have an interest in the transaction being completed. Deductions are made for costs that are directly attributable to the sale. The value in use consists of future cashflows that an asset or cash-generating unit is expected to generate. When evaluating for the purposes of impairment, assets are grouped into cash-generated units. A cash-generated unit is the smallest identifiable group with essentially independent payments. As a result, the impairment requirements of some assets are evaluated individually while others are evaluated at the level of a cash-generating unit. Goodwill is distributed across the cash-generating units that are expected to benefit from the synergies in the attributable business acquisitions and represents the lowest level at which goodwill is monitored. Impairments relating to cash-generating units initially reduce the recognised value of the goodwill that is distributed to the cash-generating unit in question. Any remaining impairment reduces the value of the other assets in the cash-generating units proportionally. With the exception of goodwill, a new assessment is made of all assets to identify signs that previous impairments are no longer justified.

<i>Tangible fixed assets</i>	%
Equipment, tools, fixtures and fittings	20

Leases

Lessee

All leases have been recognised as financial or operating leases.

Operational leases

The leasing fees under operating leases, including increased first rents but excluding expenses for services such as insurance and maintenance, are recognised as an expense on a straight-line basis over the leasing period.

Foreign Currency

Items in foreign currency

Monetary items in foreign currency are translated at the rate in force at the balance sheet date. Non-monetary items are not converted but are reported 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 involving incoming or outgoing payments.

Cash and cash equivalents are classified by the company as bank deposits.

Equity

Equity in the company consists of the following items:

Share capital, which represents the nominal value of issued and registered shares. Share premium reserves include any premiums received in connection with the issue of new share capital. Any transaction costs associated with the issue of new shares are deducted from the share premium, taking into effect any income tax effects. Development expenditure fund, which is increased annually by the amount capitalised in respect of the company's own development work. The fund is reduced annually with the depreciation of capitalised development work. Profit brought forward/Settled loss and Profit/loss for the year, i.e. all retained profits/losses and share-related compensation for the current and previous periods and the acquisition of own shares.

Note 2 Estimates and Assessments

When preparing financial statements, the Board of Directors and CEO must carry out certain estimations, assessments and make certain assumptions in accordance with the accounting and valuation principles in place which have an impact on the reporting and valuation of assets, provisions, liabilities, income and costs. The areas in which such estimations and assessments may be of great importance to the company and may thus affect future profit/loss accounts and balance sheets are set out below.

Important Assessments

The following are important assessments that have been made during implementation of the company's accounting principles, and which have the most significant effect on the financial reports.

Capitalisation of Intangible Assets

In order to assess possible impairment requirements in any intangible asset, a recoverable value is calculated on the basis of the anticipated future cashflow using an appropriate rate of interest in order to discount cashflow. In this assessment, which extends a number of years into the future, there is a degree of uncertainty in relation to future cashflows and the assessment of an appropriate discount rate. However, the company's view is that based on the information we currently possess, the assessment is fair and probable. The valuation is based on the plans for commercialisation. This plan is based on the plan currently in place. The risks that currently exist relate to the possibility that significant delays may be incurred in gaining approval from the medical authorities in the EU and the USA. The pricing level is considered reasonable as it is in line with the only other similar product currently available on the market, which in our assessment is based on old technology and cannot be compared to our product in terms of user-friendliness, reliability and mobility.

Note 3 Employees

Average number of employees	2021-01-01- 2021-12-31	2020-01-01- 2020-12-31
The Company	8	5
Total	8	5

Note 4 Depreciation and Impairment of Tangible and Intangible Fixed Assets

	2021-01-01- 2021-12-31	2020-01-01- 2020-12-31
<i>Depreciation according to plan distributed by asset</i>		
Patents	45 535	58 106
Equipment	188 151	214 729
	233 686	272 835
Total	233 686	272 835

Note 5 Capitalised Expenses for Development and Similar Work

	2021-12-31	2020-12-31
<i>Accumulated historical cost</i>		
-At the start of the year	53 699 627	40 064 402
-Investments	18 347 669	13 635 225
At the end of the year	72 047 296	53 699 627
-At the start of the year-		
Accumulated depreciation		
-At the start of the year	- 3 637 521	- 3 637 521
-Depreciation for the year		
At the end of the year	- 3 637 521	- 3 637 521
Carrying amount at the end of the year	68 409 775	50 062 106

Note 6 Concessions, Patents, Licences, Trademarks and Similar Rights

	2021-12-31	2020-12-31
<i>Accumulated historical cost</i>		
-At the start of the year	4 079 237	2 950 298
-Investments	1 239 745	1 128 939
-Disposal and scrapping-		
At the end of the year	5 318 982	4 079 237
Accumulated depreciation		
-At the start of the year	- 279 659	-221 553
-Reversed depreciation on disposal and scrapping-		
-Depreciation for the year	-45 535	-58 106
At the end of the year	-279 659	-279 659
Carrying amount at the end of the year	4 993 788	3 799 578

Note 7 Fixtures and Fittings, Tools and Installations

	2021-12-31	2020-12-31
<i>Accumulated historical cost</i>		
-At the start of the year	840 309	840 309
	840 309	840 309
Accumulated depreciation		
-At the start of the year	-561 209	-346 480
-Depreciation for the year	-188 151	-214 729
	- 749 360	-561 209
Carrying amount at the end of the year	90 949	279 100

Note 8 Non-Current Liabilities

	2021-12-31	2020-12-31
Liabilities that mature later than one year from the balance sheet date but within five years:		
Other liabilities to credit institutions	2 173 913	2 484 468
Liabilities that mature later than five years from the balance sheet date		
Other liabilities to credit institutions	-	310 564

Note 9 Accrued Expenses and Deferred Income

	2021-12-31	2020-12-31
Accrued Salaries	131 420	
Accrued holiday pay	380 959	184 614
Employer fees holiday pay liabilities	119 697	58 006
Other accrued expenses	640 179	980 445
	1 272 255	1 223 065

Note 10 Pledged Assets and Contingent Liabilities

Pledged assets	2021-12-31	2020-12-31
<i>To secure own liabilities and provisions</i>		
Corporate mortgages	4 200 000	4 200 000
Total pledged assets	4 200 000	4 200 000

Note 11 Significant Events After the End of the Financial Year

In the view of the Board of Directors, the COVID-19 pandemic may have a negative impact on the company's results for 2022, but the Board is unable to make an assessment at present as to how great such an impact may be. The primary impacts are on partnerships with other stakeholders and the possibility of delays in the project.

The Board of Directors is actively monitoring developments and implementing measures on an ongoing basis in order to limit any negative impact.

At the end of February 2022 Realheart, together with Berlin Heart, were granted around 10 MSEK from the EU-programme Eurostars 3. The grant will be used to create an automated manufacturing process for membranes.

At the end of February our chairman of the board passed away following a sudden illness. Göran was a much appreciated leader and colleague and will be missed by all of us. Realheart would not have been where we are today without Göran's vision, wisdom and energy.

In March a subsidiary was started in Australia in order to lead the controller-development.

Note 12 Key Ratio Definitions

Balance sheet total:
Total assets.

Equity/assets ratio:
(Total equity + 78.6% of untaxed reserves)/Total assets.

Cash-to-current liabilities ratio
Current assets excluding inventories and ongoing work/ Current liabilities.

Board of Directors



Christer Norström

Acting Chairman

Holding: -



Azad Najar

Board Member

Holding: 3 225 135 shares



Susanne Hedman

Board Member

Holding: 136 483 shares



Ulf Grape

Board Member

Holding: -

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