2024
Annual Report

Realheart®

Realheart ®TAH - the world's first total artificial heart that mimics the structure and pumping mechanism of the human heart.

Content

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

Disclaimer

Images in the annual report show photo models demonstrating the Realheart® TAH. Both the implanted heart pump and the external patient unit are under development and not yet approved for clinical use.

CEO Ina Laura Perkins with Realheart® TAH.

CEO Ina Laura Perkins

2024 was an eventful year for Realheart in our mission to offer a meaningful treatment alternative for patients with severe heart failure. We made strong progress in the development of Realheart® TAH, including securing SEK 4.1 million in research grants, expanding our preclinical safety testing via collaborations with leading centers in Gothenburg and Hannover, presenting new performance data, and receiving a new patent approval. In early 2025, we proudly announced that Realheart® TAH had received FDA HUD designation and that our implantation studies surpassed previous benchmarks in duration and performance. These achievements position us for a pivotal year ahead, focusing on production and product quality, as we move toward small-scale human clinical trials.

Realheart is among the few global players developing artificial organs that can replicate the natural heart's function. Our device uniquely mimics the human heart's structure and pulsatile blood flow, designed to reduce blood damage and protect vascular health. We believe these features are critical for clinical success and patient safety.

Scientific Progress and Collaborations Help Position Realheart® TAH Globally

Our progress is made possible by close collaboration with experts in medicine and engineering, including, among others, the Royal Institute of Technology (KTH), Sweden, and University of Bath, England. In 2024, we presented compelling preclinical data showing that Realheart® TAH is gentler on red blood cells and clotting factors (vWF) than competing technologies. We also demonstrated superior adaptability of cardiac output and a more stable blood pressure response during exercise and sleep, suggesting the device is well-suited to adjust to everyday activities.

A key enabler of our research and development efforts is targeted, soft funding. In May, we secured SEK 4 million from Vinnova, in partnership with the Royal Institute of Technology, to support both our clinical strategy and the development of MINIheart, a smaller version of Realheart® TAH – giving patients of all body sizes the opportunity to receive a completely artificial heart.

Preclinical Implantation Studies Indicate Treatment Safety

Realheart® TAH is developed as a bridge-to-transplant treatment for patients awaiting a donor heart. Over the past year, we have demonstrated reliable cardiac performance, adaptive function during rest and activity, and stable biochemistry over time – critical indicators of the device's safety and efficacy. Simultaneously, we have refined the surgical technique to facilitate clinical adoption. In 2025, we will continue our implantation studies in collaboration with the clinics interested in conducting our First-In-Human studies to further validate the system.

Pathway to First-in-Human Studies

To accelerate toward human trials, we supported a successful ethics application for short-term animal studies in Gothenburg. These studies will provide the initial results needed to apply for multi-day testing and survival evaluation. Together with our valued partners, we believe these efforts will bring us significantly closer to initiating clinical studies in humans.

FDA HUD Designation – an Important Platform for Dialogue

In January 2025, the FDA granted Realheart® TAH Humanitarian Use Device (HUD) designation, making it eligible for the Humanitarian Device Exemption (HDE) – an expedited approval path for medical devices. We are now engaged in regulatory discussions with the FDA to define the clinical path forward for U.S. market entry.

Strengthened Financial Base for our Continued Success

In July 2024, we completed a preferred rights issue totaling SEK 19.6 million, and in March 2025, we completed a directed share issue totaling approximately SEK 30.2 million from new and existing long-term investors. This funding enables us to reach key milestones in 2025, including increasing the quality in our production, regulatory advancements, and focusing on our reliability studies. It reflects strong confidence in our vision and supports our progress at this crucial stage. In summary, we see opportunities to take new important steps forward toward realizing our vision – that no one should die from heart failure.

Ina Laura Perkins
CEO, Realheart

No One Should Die of Heart Failure

A Global Need

Realheart® TAH will be used to save the lives of patients with advanced heart failure. Initially as a Bridge-To-Transplant (BTB) while waiting for a donated heart but eventually also as a permanent treatment. Heart failure is a fatal disease in which the heart can no longer pump as much blood as the body needs. 64 million patients worldwide are affected by heart failure. Half of all newly diagnosed patients are expected to die within 5 years of diagnosis. In the US, for example, this equates to 300,000 annual deaths. Frequent hospitalizations lead to huge healthcare costs, which including societal costs are estimated to reach USD 70 billion by 2030 in the US alone.

The only cure for advanced heart failure is a new heart, but only 8,000 donated hearts are available for transplantation globally each year. Not all patients make it onto the waiting list for a new heart, and if they do, they risk dying before a heart is available. Organ transplantation is simply not a sustainable solution, so doctors and surgeons need new safe and reliable alternatives available in the form of artificial hearts.

Our Natural Heart

Our natural heart consists of two pumps, one on the left and one on the right. Each pump consists of an atrium and a ventricle. The left pump moves blood to the systemic circulation and the right pump moves blood to the pulmonary circulation. The blood is pumped as pulses while the blood returns to the heart to facilitate uninterrupted venous return.

The human heart has two pumps - one on the left side and one on the right side. Each pump has an atrium and a ventricle. The left pump sends the blood out to the body's circulatory system, while the right sends it to the lungs. The heart pumps the blood out in pulses, while new blood is constantly flowing back without interruption.

Realheart® TAH - Mimics the Human Heart

Realheart® TAH is the first total artificial heart (TAH) designed to mimic the structure and function of the human heart. Its unique patented dual-atrial, dual-chamber design allows it to pump blood in a natural way. Tests show that these unique features help reduce blood damage-related side effects. With a lightweight, quiet and flexible controller with a long battery life, the system is designed to allow the patient to live a normal life with a good quality of life.

Realheart® TAH will be fully integrated into the human body, replacing the natural heart and delivering blood to various organs in the same primary way as the natural heart. Outside the body, there is a battery and control unit that the patient can easily carry over the shoulder or in a bag. Battery life is expected to be approximately 12 hours.

Realheart® TAH is initially intended for severely ill heart failure patients who are on the waiting list for a transplant, but who are at risk of dying if they do not receive a new heart. Thereafter, Realheart® TAH will also serve as a permanent treatment.

As a patient, you should to be able to live a normal life with Realheart® TAH.

The **Unique Advantages** of Realheart® TAH Compared to Competitors

NATURAL

A four-chamber system that mimics a human heart in structure and function.

ADAPTATIVE

Adaptable to each patient's blood flow needs thanks to intelligent sensors.

SIMPLE

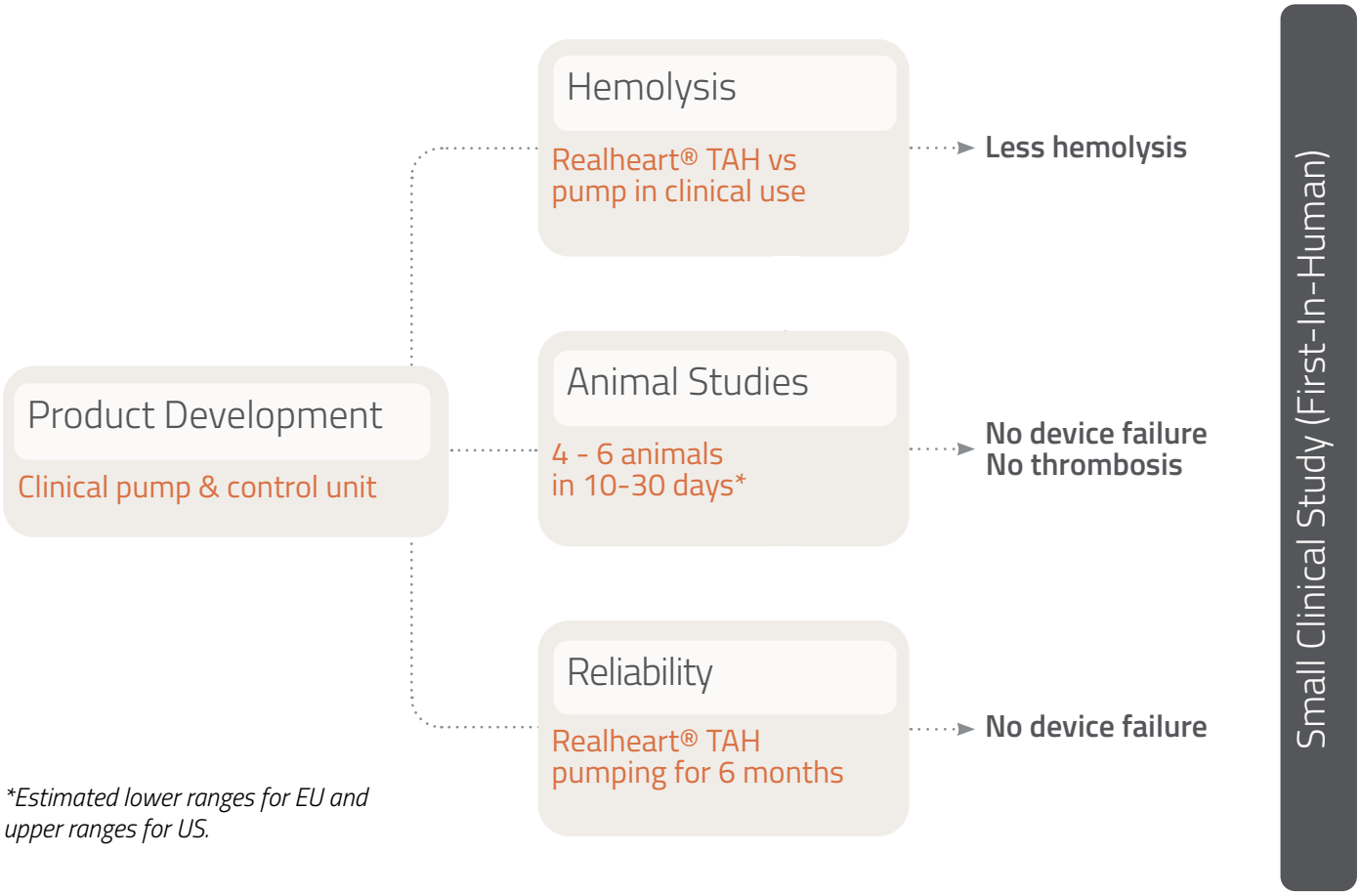
Designed with the patient in mind to create the best conditions for a good quality of life.

Feature	SynCardia	Carmat	BiVACOR	Realheart	
Flow	Co-Pulsatile	Counter Pulsatile	Continuous	Co-Pulsatile	Natural
Atria	No	No	No	Present	
Valves	4 Mechanical Valves	4 Bioprosthetic Valves	None	4 Mechanical Valves	
Cardiac Output Regulation	No	Yes	Yes, with limitations**	Yes	Adaptative
Atrial Pressure Regulation	No	Partially	No	Yes	
Suction Avoidance	No	Partially	Limited	Yes	
External Weight	~ 7 kg/15 kg	~ 4 kg/8.5 kg	~ 4 kg/8.5 kg	1 kg/2.5 kg	Simple
Cables	2 Percutaneous Cables	1 Percutaneous + 2 Battery Cables	1 Percutaneous + 2 Battery Cables	1 Percutaneous Cable (no battery cable)	
Sound Level	Loud (75 dB)	Silent	Silent	Silent	
Battery Life	3h	4h	8h	12h (5h+7h spare battery)	
Infection Risk	High Risk, 2 Stiff Cables (2x10 mm)	Low Risk, 1 Stiff Cable (8 mm)	Medium Risk, 1 Stiff Cable (10 mm)	Lowest Risk, Single Flexible Cable (-6 mm)	

***https://pubmed.ncbi.nlm.nih.gov/18959670/*

We Aim for **FDA Approval** and **CE Marking** for Destination Therapy and Bridge to Transplant

The basic design of the Realheart® TAH is fully developed. To verify the design and its function, preclinical results from endurance tests, blood tests and long-term animal studies are required. These studies are being conducted in parallel. The purpose of the animal studies is to wake up the animal and observe it while it is living with the artificial heart. The length of time the animal must be kept alive is determined by the regulatory authorities.



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

Preclinical Studies

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

Preparing for Clinical Trials

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

First-In-Human

SMALL CLINICAL STUDY

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

Product Development

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

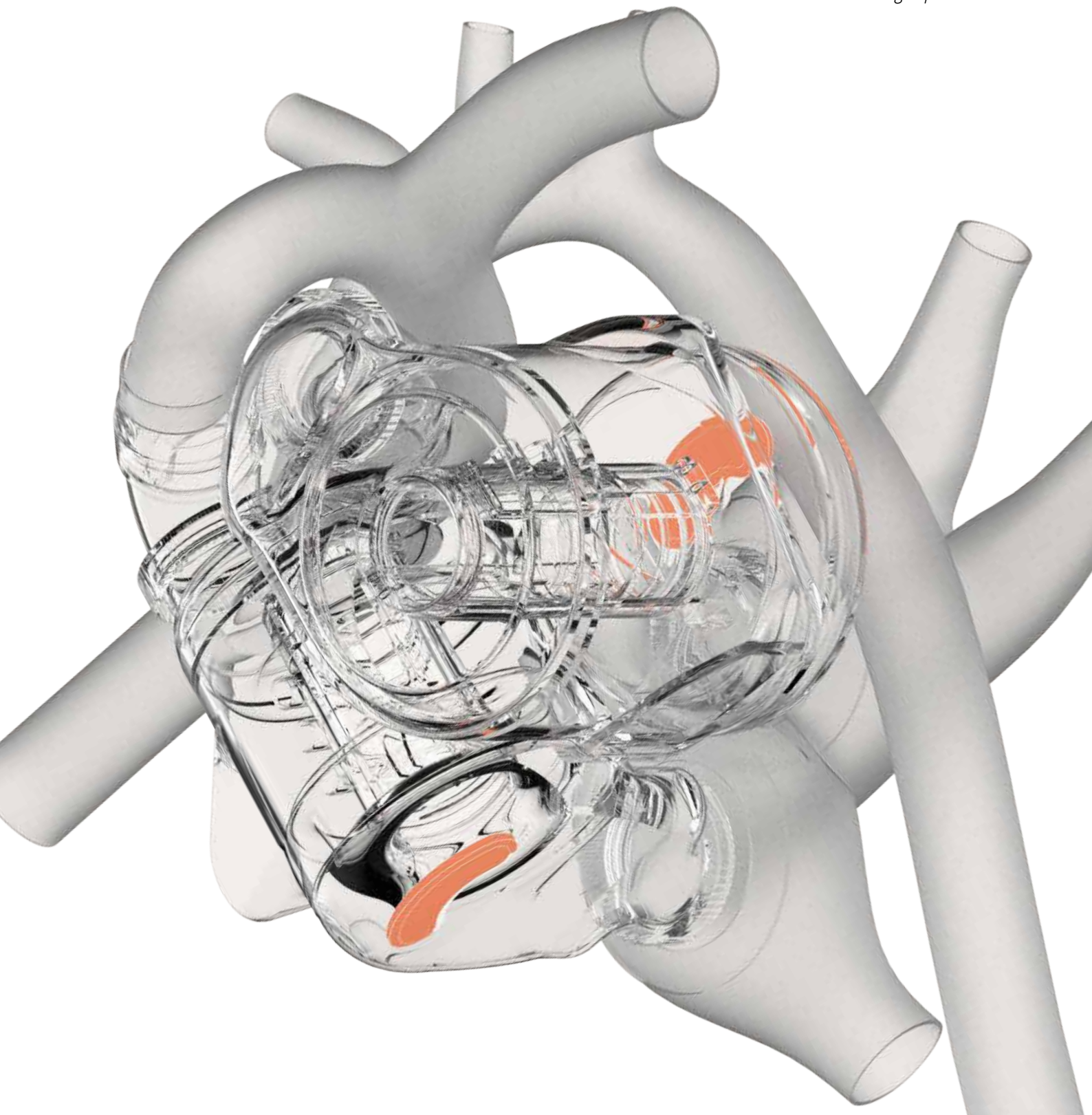
BTT IDE (PMA) Study & CE Marking

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

Activities for Market Launch

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

Rendered image of Realheart® TAH.



Research, **Development** & Cooperation

Realheart works devotedly to drive advances in artificial hearts through groundbreaking research, technological development and strategic collaborations.

Research in general aims to improve treatment options for patients with severe heart failure, while technological development specifically focuses on creating an artificial heart that mimics the structure and function of the human heart.

Close collaborations with leading universities, hospitals and medical experts ensure that the Realheart® TAH innovation is based on the latest technology and science to be ready for future clinical trials.

Research to Improve Treatment Options

Positive Results From Another Successful Preclinical Study

The company has successfully completed another implantation of the artificial heart Realheart® TAH within the framework of the preclinical program that will form the basis for the first clinical study in patients. The results show that Realheart® TAH gives rise to good cardiac function and low levels of adverse blood events, while the survival time of the implanted animal exceeded previous trials. Overall, the results support that Realheart® TAH has good potential to replace the human heart in the future.

After implantation, several positive results were measured regarding the performance of the artificial heart, including good cardiac output, proper blood pressure control and balance between the oxygen-rich and oxygen-poor side of the circulatory system.

In accordance with previously presented data, the level of hemolysis is below the threshold, i.e. little harmful impact on red blood cells. Being able to document a hemolysis below the cut-off value is an important regulatory requirement for conducting clinical studies in patients. The 7-day survival time was increased compared to previous trials and no signs of kidney injury was observed. The operation was carried out by Realheart's collaborating cardiac surgeons, including Prof. Bart Meyns and Dr. Dilek Gürsoy.

Dr Ulf Kjellman, Chief Medical Officer

We are very pleased with the results showing that Realheart® TAH can restore good systemic circulation without serious side effects. This type of complex trial is conducted under the strict ethical guidelines that surround animal experimentation, and each successful operation provides new invaluable insights that help us move forward in development. The surgeons in charge describe Realheart® TAH as very easy and efficient to work with, and the results meet both their and our high expectations. We are now working to further improve the surgical protocol and look forward to presenting new results as soon as possible.

New Studies and Results on Simulation Data, Unique Computational Model and Treatment Safety in Preclinical Studies

Simulation Data Show Superior Efficacy During Exercise and Sleep

The study used Scandinavia's first simulated patient (hybrid simulator), connected to a virtual model of the human cardiovascular system to evaluate the ability of the Realheart® TAH to adapt to the patient's varying physiological needs, e.g. to respond to higher blood flow demands during moderate exercise and to sleep compared to the market-leading product. The results showed that Realheart® TAH produces a higher CO, like that of the natural heart, and a more stable MAP compared to the competing system during moderate exercise, and reduced CO during simulated sleep.

The hybrid simulator was developed by KTH in a joint research project funded by the program Smart Elektronik, a joint initiative by Vinnova, Formas, and Energimyndigheten. Collaborating researchers (Prof. Seraina Dual) at KTH Royal Institute of Technology evaluate the performance of the TAH by measuring cardiac output (CO), the amount of blood pumped through the TAH per minute, and mean arterial pressure (MAP), the average blood pressure in the arteries.

"This is very promising data as it is likely that patients will have a better quality of life if the artificial heart can automatically adapt to the body's activity level. We are committed to developing an artificial heart that mimics the physiological heart as much as possible, and the research results presented at the ISMCS meeting demonstrate yet another aspect in which we are successful in this ambition. "

Ina Laura Perkins, CEO at Realheart

Unique Computational Model Awarded ESAO-SAGE Research Prize

The company published a preclinical study describing a new method for simulating hemolysis in artificial hearts using pumping mechanisms. This unique approach will be important in the further development of Realheart® TAH. Based on its innovative approach, the study was awarded the ESAO-SAGE Research Prize at the 50th Congress of the European Society for Artificial Organs in 2024. The winner was selected by a special committee based on a manuscript published in the International Journal for Artificial Organs.

The degradation of red blood cells (hemolysis) in mechanical blood circulating devices (MCS) remains a safety issue due to the side effects that can occur, such as blood clots. It is therefore important to reduce the risk of hemolysis in heart pumps seeking regulatory approval for clinical use. In a new study, Realheart, together with its academic partner the University of Bath, described a newly developed simulation model for MCS that uses reciprocating (positive displacement) pumping mechanisms. Such simulations have historically been based on devices that spin to pump blood, limiting the applicability of Realheart® TAH. This new approach and the study results will be important to further improve the hemolytic profile of Realheart® TAH and to provide important safety information to regulatory authorities.

Preservation of von Willebrand Factor (vWF) and Realheart® TAH's Ability to Adapt to Patient Needs

As part of the preclinical development program for Realheart® TAH, the Company evaluated the artificial heart's overall effect on human blood, as well as its ability to respond to varying blood flow needs of the cardiovascular system. The current studies compared the performance of Realheart® TAH with a continuous flow pump and with the current market-leading device.

The results of the first study showed that pulsatile pumps like Realheart® TAH preserves functionality of von Willebrand factor (vWF) - a protein that is important for blood clotting and preventing internal bleeding, whereas the continuous flow pump reduced the function of vWF. Internal bleeding is a common and troublesome side effect of the heart pumps available today. Therefore, it is important to protect the blood clotting proteins. In addition, the study confirmed previously reported data that Realheart® TAH is gentle on the blood as red blood cells are subjected to low mechanical stress (shear stress), resulting in low levels of blood damage (hemolysis) compared to the competing system.

New Important Collaborations and New Patent Approval

Veterinary Medicine Center at the University of Gothenburg

The company initiated a collaboration with a leading veterinary large animal unit at the University of Gothenburg in Sweden for the continued preclinical safety evaluation of Realheart® TAH. The aim is to improve the study protocol by conducting experiments focusing on evaluating the surgical technique. This will also facilitate the preparation of the clinical trial planned to be conducted in Sweden.

The company has so far conducted all implant trials with Realheart® TAH at a veterinary center in Belgium that has long and broad experience of both preclinical surgical procedures and interactions with regulatory authorities in the United States and Europe. The collaboration with this institution will continue during the further preclinical development. The expansion of the safety evaluation to a Swedish institution means increased proximity to and strengthened collaboration with the surgical team that will participate in future clinical studies. This has significant benefits for further development and with the ethical approval in place the next step in the collaboration is to initiate the surgical evaluation.

Hannover Medical School in Germany

Collaboration was also initiated with Professors Arjang Ruhparwar and Jan Schmitto, at the Department of Cardiothoracic Surgery, Transplantation and Vascular Surgery at Hannover Medical School, Hannover, Germany. The collaboration aims to familiarize leading transplant surgeons with Realheart® TAH and gain valuable professional input for clinical trials and potential launch of Realheart® TAH.

The Department of Cardiothoracic, Transplantation and Vascular Surgery (HTTG) at Hannover Medical School is considered one of the leading medical centers in the world and specializes in the treatment of complex cardiac indications and heart diseases. Under the agreement, HTTG will act as an advisor and, in due course, potentially participate in the company's clinical evaluation of Realheart® TAH. The next step is to apply for ethical approval to initiate surgical training in animal experiments.

Patent Approval in India

The approved patent relates to a vascular coupling device, which is used to connect the Realheart® TAH to the major vessels of the circulatory system in the context of surgical implantation. The validity of the patent (No. 552361) is 20 years, which means it will expire in April 2042.

Prof. Jan Schmitto

Total artificial hearts represent a new and important category of devices that will help fulfill the great medical need for patients waiting for a heart transplant. My team and I look forward to getting to know the Realheart® TAH in detail, to provide new insights into its development and hopefully evaluate the device in a future clinical study.

Dr. Ulf Kjellman presenting Realheart at China International Import Expo (CIIE) conference.

National & International **Marketing**

Realheart works actively to spread knowledge and raise awareness of heart failure and the enormous need for innovative treatment options that exist, both in Sweden and globally.

Through strategic marketing and close dialog with surgeons and other health-care professionals, patients and investors, Realheart strengthens its position in the international Medtech arena.

All collaborations and activities aim to create confidence in Realheart as a company and in Realheart® TAH as a technical innovation and thus pave the way for its future clinical use worldwide.

New Updated Safety Data Presented at Global Medtech Conferences

American Society for Artificial Internal Organs (ASAIO) 70th Annual Conference

During the conference, which took place in Baltimore, Realheart presented new hematology study data that strengthen the company's previous findings, showing that Realheart® TAH has a low harmful impact on red blood cells (hemolysis) compared to today's market-dominant heart pump systems. The new results were based on in-depth analyses including several blood components and further confirm that Realheart® TAH causes a significantly lower degree of blood damage.

The annual conference, organized by the American Society for Artificial Internal Organs (ASAIO), brought together the world's leading scientists, clinicians, engineers and entrepreneurs in the field of artificial organ development. The conference was also attended by representatives from the US Food and Drug Administration (FDA) and other public institutions.

International Society for Mechanical Circulatory Support (ISMCS)

Another highly relevant conference was ISMCS, where Realheart, at the 30th Annual Meeting in 2024, presented updated safety data from a preclinical study with Realheart® TAH. At the meeting, the Company's R&D engineer Faisal Zaman was nominated for the Helmut Reul Young Investigator Award, a prestigious prize that rewards groundbreaking innovation.

Realheart Awarded Almi Guldstänk as Innovator of the Year

In the spring, Realheart was awarded the prize as Innovator of the Year 2023 in the regional competition Almi Guldstänk. Realheart was nominated based on the jury's motivation, which highlights the company's development of the groundbreaking artificial heart Realheart® TAH. The motivation was: "The Innovator of the Year has with determination and patience gotten to where they are today. With a strong innovative force and a determined team, they have attracted international attention and the whole world is their market. People talk about making history, but this is where the future grows. With the voice of the people behind them, they are keeping up the pressure. And listen carefully and you will hear, the heart beats for Västerås."

Guldstänk is a networking event and competition organized by Almi Mälardalen, Företagarna Västerås, Handelskammaren Mälardalen, Marknadsföreningen i Västerås and Västerås city to celebrate local entrepreneurs. The awards are given to reward entrepreneurs and organizations based in the region and are awarded to nominees voted for in a public ballot.

Investor Presentations, Interviews & Success Magazine

LSX Nordic Congress

Do we have gender equality in health? That was the main question for the panel discussion on Nordic perspectives on women's health at the LSX Nordic Congress. And the short answer was no - at least not yet. Realheart CEO Ina Laura Perkins was one of the keynote speakers on the panel along with companies SmiLe Venture Hub, Sigrid Therapeutics and OSAIA Health.

Key questions discussed during the session were:
- How are the Nordic countries driving the development of technologies, treatments and approaches that specifically address the unique healthcare needs of women?
- What challenges do Nordic countries face in achieving gender equality in health and what strategies are in place to overcome these barriers?
- What lessons can other regions learn from the Nordic approach and what lies ahead in the continued pursuit of gender-inclusive health systems?

Ina Laura Perkins highlighted, among other things, the need to look at the products already on the market for female patients, as most of them have been originally developed for men and moderator Anette Steenberg summarized that what we need is (still) earmarked funds, already at the research level, and regulation to achieve gender equality in health.

LSX Nordic brings together life science and healthcare industry leaders with international investors and strategic partners to promote the growth, development and internationalization of Nordic and Baltic life science and healthcare innovation. The aim is to facilitate increasing international investment in the region and to foster strategic partnerships and collaboration with key international healthcare stakeholders.

Aktiespararna, FS Markets & Infront Direkt Studios

Realheart also presented the Company at Aktiespararnas 'Stora Aktiedagarna' in Stockholm in November, an investor activity that brought together around 150 existing and new investors. CEO Ina Laura Perkins presented a series of very positive test results from preclinical studies. Potential technical risks, continued operation and patient recruitment were questions she provided clear answers to. She also presented several arguments for why you should be interested in the company right now.

With the theme "Invest like the Pros", Realheart participated at FS Markets in the form of an investor presentation in front of a packed room.

In connection with the release of reports, issues or other relevant events in the Company, CEO Ina Laura Perkins has been present at Direkt Studios for interviews. These productions have been disseminated in Direkt Studios' own channels as well as in Realheart's channels.

'Högvarv' Labor Market Fair

"Discover the meaning of a total artificial heart and understand the complex technology." The interest in the company's business in general and the artificial heart in particular was very high when Realheart participated on site at Högvarv's Labor Market Fair at Mälardalen University (MDH) to answer questions, but also to give visitors the opportunity to see and feel the artificial heart Realheart® TAH up close. Many were also wondering about the opportunities for internships and thesis work.

> This is a very good platform for us as a company to operate on as we are looking for both students for ex-jobs and future employees in this high-tech field. It is difficult to recruit the excellence we need, so it is extra valuable to be in a place where we directly meet students with a technical focus and a specific interest in medical devices.
>
> *Oliver Chu, Principal Engineer at Realheart*

"Framgång" Magazine

Realheart founder and innovator Azad Najar was proud to be featured in the latest issue of Framgång, the business magazine published by Västmanlands läns tidning (VLT). In it, we could read about Azad's journey from idea to medical school and his tireless commitment to helping heart failure patients. Among other things, Azad highlighted Sweden's fantastic innovation infrastructure and he received early support from both Almi and Nyföretagarcentrum.

Realheart® TAH held by a hand.

Thomas Finocchiaro and Soteris Andreou in Realheart's laboratory in Västerås, Sweden.

Team & Recruitments

Realheart's competent team is its greatest strength, which is also reflected in the breadth of expertise from around the world.

During the year, the Company has continued to grow and further strengthen its expertise, including through strategic recruitments and collaborations that ensure that the Company has the right expertise to drive the development and commercialization of Realheart® TAH forward - from preclinical studies to clinical use.

The shared commitment and passion for innovation, together with the vision that no one should die from heart failure, makes the team ready for the next step.

New Recruitments in Both Team and Board

Realheart's CFO - From Jonas Caspari Bark via Andreas Hultdin, to the Current Jimmy Nybom as Interim CFO

When Jonas Caspari Bark left the role of Chief Financial Officer to take up a senior role in another company, Andreas Hultdin took over as interim CFO. Andreas Hultdin's background is an MBA from Umeå University, several senior financial roles, including Group Accounting Manager at ABB and Financial Manager at ABB Norden Holding, before the current position as CEO of the consulting company Nogap. Between 2019 and 2022, he was CFO at Realheart and contributed to securing funding from the European Investment Council (EIC).

When Andreas Hultdin left, Jimmy Nybom took over the role in September and is holding it during the ongoing recruitment process of a permanent CFO.

Jimmy Nybom's background is a Master of Science in Business Administration with a specialization in accounting and finance from Umeå University. He has previous experience as interim CFO and board member in the public company sphere and 18 years of experience as an auditor and advisor at the global audit firm Grant Thornton, where he has had extensive contacts with Realheart as the company's auditor during the years 2019-2022 and is therefore well acquainted with the company's finances and operations.

Magnus Öhman Strengthens Realheart's Board of Directors and Takes on the Role of Executive Chairman

Magnus Öhman was appointed by the Company's Board of Directors as Executive Chairman of the Board, thereby assuming an active role in the Company's operational work to develop and commercialize Realheart® TAH.

"As we approach the clinical development phase of Realheart's artificial heart, we are taking a step closer to the commercial market and are therefore keen to strengthen our operational capacity in these areas. Magnus Öhman's solid experience of leading and developing medical device companies is invaluable and in his new role he will be able to further contribute to the ongoing transformation of Realheart."

Christer Norström, Realheart's outgoing Chairman of the Board

Magnus Öhman has extensive experience from the medical device industry. He has, among other things, been CEO of St. Jude Medical's Swedish subsidiary in Cardiac Rhythm Management, with over 600 employees and a turnover of approximately SEK 5 billion.

Magnus Öhman, Chairman of the Board

Realheart's artificial heart has enormous potential to address complex and comprehensive medical needs in today's cardiac care. In my view, Realheart is ready to take the next step forward and I am therefore very much looking forward to becoming part of the operational business and at the same time leading the overall strategy work in my new role as Executive Chairman of the Board.

Realheart® TAH is tested against leading heart pump systems in the Company's laboratory.

Grants & Share Issues

To drive the development of Realheart® TAH forward, in addition to the innovation itself, strong and secure financing is required. During the year, several important grants have been secured, strategic loans have been taken and share issues have been carried out, which give the Company resources to continue the important work towards clinical studies.

The support of investors and financial partners is crucial to the continued development of life-saving technology and to ultimately give more patients a second chance at a better life.

Vinnova Grants & Successful Issues

Realheart Receives Two Grants From Vinnova

One of the grants from Vinnova, of approximately SEK 100,000, was awarded within the framework of a competence-strengthening grant, funded by Medtech4Health, a strategic innovation program aimed at strengthening the medical technology industry. The program aims to enable the clinical implementation of medical technology ideas and solutions in consultation with healthcare, academia and industry. The grant will be used to support the development of production processes for Realheart® TAH.

As Realheart takes steps forward in the preclinical development of Realheart® TAH, the company is approaching a phase where there is a clear need to establish a validated production process. Therefore, a project is underway to develop a high-quality and scalable manufacturing method that will eventually enable a continuous production flow. The grant from Vinnova will finance a part-time consultancy position for a mechanical engineer with specialized expertise in process and production development of implantable medical devices. The person in question has previous experience in leading and supporting this type of development project.

Another grant from Vinnova was for SEK 4 million, which Realheart received together with the Royal Institute of Technology (KTH) with the aim of further developing the company's transplant system. A project that runs for two years.

Realheart has been awarded Vinnova's Smart Electronics grant on a previous occasion, then with the aim of constructing a unique digital model of the human heart, lungs and blood vessels (hybrid simulator) with the capacity to evaluate the function of Realheart® TAH in varying disease types and patient sizes. Based on the simulator tests, the company has gained increased knowledge of how Realheart® TAH works under different disease conditions and the technical requirements that follow from different size changes of the implant.

The grant amounts to SEK 4 million and will be paid out in stages over the next two years. With the help of the grant, Realheart together with the Department of Medical Technology and Health Systems at KTH will use the hybrid generator to generate new comparative data between Realheart® TAH and a competing heart pump system. This new data will play an important role in the company's marketing towards clinical staff and potential investors. Furthermore, the project will take the next step in the development of MINIheart, a smaller version of Realheart® TAH, adapted for patients with smaller body size, including through miniaturization of the device's electronics.

Successful Rights Issue and Directed Share Issue to Guarantor

On May 7, 2024, Realheart decided to carry out a rights issue of a maximum of 193,988,892 shares with preferential rights for existing shareholders. The subscription price in the issue was set at SEK 0.5 per unit, which meant that the issue comprises a total of 96,994,446 units consisting of two (2) newly issued shares and one (1) warrant of series TO3. Full subscription meant that the Company would receive approximately SEK 48.5 million before issue costs.

The subscription period ran between June 12 and July 5, 2024, and the issue was approximately 50 percent guaranteed through guarantee commitments and subscription commitments from existing shareholders and external investors.

Outcome in the Rights Issue – in Total 50.1 Percent of the Rights Issue

The final outcome showed that 38 083 456 units had been subscribed for with support of unit rights, corresponding to approximately 39.3 percent of the Rights Issue. Additionally, we received applications for subscription of 5 527 237 units without support of unit rights, corresponding to approximately 5.7 percent of the Rights Issue. Consequently, 43 610 693 units were subscribed with and without unit rights, corresponding to approximately 45.0 percent of the Rights Issue. Underwriting commitments of 4 999 713 units was exercised, corresponding to 5.2 percent of the Rights Issue. In total, 48 610 406 units were subscribed, corresponding to 97 220 812 newly issued shares and 48 610 406 warrants of series TO3. Through the Rights Issue the company received SEK 19.6 million after direct issue costs.

In addition, Realheart carried out a directed share issue of 6,300,000 units as guarantee compensation to the participants who provided guarantee commitments in connection with the rights issue. Warrants of series TO3 were also issued to the underwriters, which entitled to subscription of a maximum of 3,150,000 shares.

Rendered image of Realheart® TAH.

Zoltán Szabó, Realheart Medical Advisory Board, Dr. Ulf Kjellman, Realheart Chief Medical Officer and Prof Emeritius Henrik Ahn, Realheart Medical Advisory Board.

Board of Directors

Magnus Öhman

Chairman since March 11, 2024

Holdings: 9 000 shares, 40 000 TO3

Azad Najar

Board Member

Holdings: 31 806 shares

Solveig Bergström

Board Member

Holdings: -

Oliver Voigt

Board Member

Holdings: 32 shares

Stuart McConchie

Board Member

Holdings: -

Giovanni Lauricella

Board Member

Holdings: -

Christer Norström

Board Member during the period January 1, 2024 - June 7, 2024, of which as Chairman until March 10, 2024.

Ulf Grape

Board Member during the period Jan 1, 2024 - June 7, 2024.

The shareholding relates to current board members, as of March 31, 2025.

Scandinavian **Real Heart** AB

Swedish innovation power has given the world medical technology inventions such as the heart and lung machine, the pacemaker and the dialysis machine. The next big innovation is Realheart's artificial heart. A Swedish patented innovation that will save the lives of heart failure patients. Every year, 3,500 people die of heart failure in Sweden alone. Today, the only rescue is a heart transplant, but the number of donated hearts is only enough for 2% of those in need.

The start-up of the Company was initiated by the doctor and inventor Azad Najar in 1999 when he started sketching an artificial heart that completely mimics the biological. In 2007, Azad co-founded Scandinavian Real Heart with two partners. The original idea behind Realheart® TAH is based on flow analyzes made at KTH 2002-2005 and is based on constructing an artificial heart that mimics the biological. By imitating its basic principle, a pressure and flow is created that reduces the risk of blood clots and provides an energy-efficient blood flow. These factors are important to give the patient a good quality of life. The development of the product has progressed strongly over the years. Blood circulation, pump function, pressure, and pulse generation have been verified in ethically approved animal experiments. Today, research and development takes place in close collaboration with world-leading heart surgeons, researchers and engineers.

Patent Protection

Realheart has patent protection on the original pump principle in the US, UK, Sweden and Germany. Patents have been granted in Sweden, the EU, the US and China to protect the latest version of the Realheart® TAH. A patent for a pressure sensor for artificial hearts and circulatory support systems such as Realheart® TAH has been approved in Japan. The patent is a support measure to ensure market protection for the company's device in the Japanese market and is valid until 2041. Patent applications have also been filed for Australia, Canada and India. These markets are the largest and most important for artificial hearts at the moment, with the exception of China and India which are considered important emerging markets.

In addition to the patent protection described above, Realheart has also filed patent applications for future products: RealheartVAD®, Realheart PulsePump® and Realheart Sternal Prosthesis. In 2018, a new connector was designed for a simple and safe connection between the Realheart® TAH and the body's circulatory system. A patent application for this has also been filed. Given the existing patents together with the new patent applications, the Board of Directors believes that the Company has a strong patent situation and strong intellectual property protection.

Mission and Goal

Realheart's mission is to use medical technology solutions to save as many heart failure patients as possible and to create the best conditions for a life-affirming continuation of life. The Company's overall goal is for the artificial heart to be commercialized and become a full-fledged treatment alternative for patients with heart failure. The heart should have a better function than the solutions that are on the market today. It should be possible to use both as a bridge to transplantation and as final therapy.

The Stock

The share was listed on Nasdaq First North Growth Market in December 2021. Nasdaq First North GM is a registered SME marketplace for growth companies that enables Nordic and international entrepreneurs to access growth capital to develop and expand their businesses. As of December 31, 2024, the number of shares in Scandinavian Real Heart AB amounted to 2,068,152.

The patient unit of Realheart® TAH.

The patient unit of Realheart® TAH external control unit with integrated, easily exchangeable battery. Battery life is estimated at 12 hours.

Board of Director's Report

General Information About the Business

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

The Group is engaged in the development of medical products and consists of two companies, the Parent Company, which is based in Västerås, where most of the business is conducted, and the subsidiary Scandinavian Realheart Pty, which is based in the state of Victoria, Australia.

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 solution is designed to mimic the blood flow pattern and function of the natural human heart, creating the potential for 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 the company is working on a continental basis on new patents. In the case of general research not linked to product development, it is not balanced. Work on developing the heart pump for clinical trials on humans is ongoing through pre-clinical studies on animals, research and materials development.

Development of the Company's Operations, Results and Position

GROUP

Amount KSEK	2024-12-31	2023-12-31	2022-12-31
Balance sheet total	83 280	102 638	119 816
Equity ratio	81%	80%	81%
Cash liquidity	226%	321%	71%

Definitions: see note 17

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

PARENT COMPANY

Amount KSEK	2024-12-31	2023-12-31	2022-12-31	2021-12-31	2020-12-31
Balance sheet total	85 837	103 222	111 229	117 815	78 045
Equity ratio	82%	80%	88%	95%	92%
Cash liquidity	224%	309%	95%	1032%	667%

Definitions: see note 17

Significant Events During the Financial Year

Organisation and Management
In March, Magnus Öhman took over as acting chairman of Realheart's board with an active role in the company's operational work to develop and commercialize Relheart® TAH.

In August, Jimmy Nybom took over as new interim CFO. Jimmy has had extensive contacts with Realheart as the company's auditor during the years 2019-2022 and is therefore well versed in the company's finances and operations.

Research and Development Activities
Realheart has obtained new study data reinforcing the company's previous results showing that the company's artificial heart, Realheart® TAH, has a low harmful impact on red blood cells (hemolysis) compared to today's market-dominant heart pump systems. The new results are based on in-depth assays including several blood components and further confirm that Realheart® TAH causes a significantly lower degree of blood damage.

Realheart has completed another successful preclinical trial with Realheart® TAH. The results show that Realheart® TAH gives rise to good cardiac function and low levels of harmful blood effects while the survival time of the implanted animal exceeded previous trials. Overall, the results support that Realheart® TAH has good potential to replace the human heart in the future.

Realheart has entered into a collaboration with a leading veterinary large animal unit at the University of Gothenburg for the continued preclinical safety evaluation of the Realheart® TAH artificial heart. The aim is to conduct high quality experimental large animal studies required to eventually conduct a clinical trial. This will also facilitate the preparation of the clinical trial planned to be conducted in Sweden.

Realhart has published a preclinical study describing a new method to simulate hemolysis in artificial hearts using pumping mechanisms. This unique approach will be important in the further development of Realheart® TAH. Based on its innovative approach, the study was awarded the ESAO-SAGE research prize at the 50th Congress of the European Society for Artificial Organs 2024.

Realheart has initiated a collaboration with Professors Arjang Ruhparwar and Jan Schmitto, at the Department of Cardiothoracic Surgery, Transplantation and Vascular Surgery at Hannover Medical School, Hannover, Germany. The collaboration aims to familiarize leading transplant surgeons with Realheart® TAH and gain valuable professional input for the clinical trials. Realheart® TAH is intended for use in patients awaiting heart transplantation or as an alternative to transplantation.

The company has been granted an approval by the Patent Office of India for its patent application (No. 202117045813) for a technical application related to the clinical use of Realheart® TAH.

Impairment of Intangible Fixed Assets
The value of all the Group's intangible assets is tested annually or when indications of significant changes in assumptions are identified. In connection with the work on the 2023 financial statements, a careful analysis was made of the book values of the Group's operating assets, including goodwill, in relation to current WACC requirements. Due to a sharply increased interest rate level in 2023, which increases the requirements for WACC, and previously communicated delays in the commercialization process, the Board decided to write down the value of intangible assets of SEK -50.1 million. During the current year, the year's capitalized expenses for development work have been written down in full, corresponding to an amount of SEK 19 million. The write-down does not affect cash flow. An impairment of the value of intangible assets means that the requirement for future amortization is reduced, which will give a better future result

Financing
During the year, the company received SEK 19.6 million after issue costs through a rights issue. During the period, the company received the following grants:- SEK 0.1 million from Vinnova within the framework of a competence-enhancing grant. The grant, which will be used to develop production processes for Realheart® TAH, is financed by Medtech4Health, a strategic innovation program aimed at strengthening the medical technology industry.- SEK 4 million in a grant from Vinnova together with its partner at the Royal Institute of Technology (KTH) with the aim of further developing the company's transplantation system. The project runs for two years.

Patent Protection
The company has patents granted on the pump principle in Sweden, France, Germany, the United States, China, India, the United Kingdom, Australia, and Japan. In addition, the company has a further series of patent applications on the control system of the pump that are in the process of being approved in these countries. During the year, a further patent was granted in India. A new patent application for an integrated sensor for the pump was filed during the year. In total, the patent portfolio consists of nine patent families. The company already has a trademark registration for the REALHEART brand in key international markets including Australia, the EU, Canada, Japan, Norway, Switzerland, the UK and the USA.

Expected Future Developments and Significant Risks and Uncertainties
Realheart's focus remains on getting through the preclinical phase (hemolysis, safety studies and endurance tests) to be able to start clinical studies. This means that the company must finalize the version of both the controller and the heart pump to be included in these tests. Realheart is also continuing discussions with the Notified Body in the EU and with the FDA to ensure the fastest and safest route for the product to market. The company is continuously working on measures to minimize delays. Furthermore, the continued product development requires that we can continue to solve the financing.

The Company is continuously working on measures to minimize delays. It is the Board's assessment that the continued operation is currently secured. Furthermore, long-term product development requires continued future financing, which the Board is continuously working on.

Financing
In February 2025, the outcome of the subscription period for the warrants of series TO 2 ("Warrants") issued in connection with the rights issue of units carried out by the Company during the period June 20, 2023 - July 7, 2023 was announced. In total, 17,035,600 Warrants were exercised for subscription of 85,178 shares, corresponding to a subscription rate of approximately 51 percent of the total 33,495,885 issued Warrants. Through the exercise, Realheart will receive approximately SEK 721 thousand before issue costs.

In April 2025, Realheart announced the outcome of the subscription period for the warrants of series TO 3 ("Warrants") issued in connection with the rights issue of units carried out by the Company during the period June 12, 2024 - July 5, 2024. In total, 31,998,400 Warrants were exercised for subscription of 159,992 shares, corresponding to a subscription rate of approximately 58 percent of the total 54,910,406 Warrants issued. Through the exercise, Realheart will receive approximately SEK 2.1 million before issue costs.

In March 2025, the Board of Directors decided to carry out a directed share issue of up to 2,881,115 shares at a subscription price of SEK 11.31 per share. The investors in the directed share issue consist of a limited number of qualified and other professional investors, including both new and existing shareholders, including the European Investment Council, Claes Mellgren and Per Olof Andersson. During April and May, a total of 2,685,382 shares were subscribed for, raising SEK 30.4 million before transaction costs.

The Board of Directors considers that the continuation of operations is assured with the financing obtained.

Significant Events After the Financial Year

Research and Development Activities
The company's total artificial heart, Realheart® TAH, has been granted Humanitarian Use Device (HUD) designation by the US Food and Drug Administration (FDA). The HUD designation makes Realheart® TAH eligible to apply for Humanitarian Device Exemption (HDE), an expedited regulatory pathway that can grant the product special market rights.

During the month of January, Realheart has achieved successful results from a completed 7-day animal study with Realheart® TAH. The results show that the device provides adequate cardiac function, automatically adapts to rest and exercise, and maintains good blood biochemistry.

In April, Realheart was granted a patent approval by the Japan Patent Office (JPO) for a pressure sensor for artificial hearts and circulatory support systems such as Realheart® TAH. The patent is a supporting measure to ensure market protection for the company's device in the Japanese market and is valid until 2041.

Ownership* of Parent Company

	Numbers of Shares	Votes (%)	Capital (%)
European Innovation Council Accelerator	183 000	8.8%	8.8%
Avanza Pension	106 756	5.2%	5.2%
Christer Jönsson	80 000	3.9%	3.9%
Eskilstunahem Fastighets AB	79 001	3.8%	3.8%
Nordnet Pensionsförsäkring	74 975	3.6%	3.6%
Abbe Dikmen	39 832	1.9%	1.9%
Jonas Rudberg	36 653	1.8%	1.8%
Claes Mellgren	33 991	1.6%	1.6%
SIP Youplus Assurance	32 156	1.6%	1.6%
Najar Medical and Invention AB	31 559	1.5%	1.5%
Others	1 370 229	66.3%	66.3%
Total	**2 068 152**	**100.0%**	**100.0%**

**Per December 31, 2024.*

Shareholder's Equity

GROUP

	Share Capital	Other Contributed Capital	Other Equity incl. net Income
Opening Balance 2023-01-01	3 318 346	165 057 256	-70 730 380
Changes directly in equity			
Translation differences	-	-	-
Transactions with owners			
New share issue	6 381 099	46 440 397	-
Warrants, repayment	-	-28 630	-
Transfer between equity items			
Profit for the year	-	-	-67 977 292
Total Shareholders's Equity 2023-12-31	**9 699 445**	**211 469 023**	**-139 130 494**
Opening Balance 2024-01-01	9 699 445	211 469 023	-139 130 494
Changes directly in equity			
Translation differences	-	-	66 997
Transactions with owners			
New share issue	4 392 832	15 221 186	-
Reduction of share capital	-3 730 835	-	3 730 835
Warrants, repayment	-	-28 630	-
Transfer between equity items			
Profit for the year	-	-	-34 350 238
Total Shareholders's Equity 2024-12-31	**10 361 442**	**226 661 579**	**-169 682 900**

PARENT COMPANY

	Share Capital	Fund for Develop-ment Costs	Share Premium Account	Retained Earnings	Profit for the Year
Opening balance 2023-01-01 (3 318 346 shares)	3 318 346	82 226 190	165 057 256	-138 966 745	-13 810 029
Provision for development fund	-	-43 871 435	-	43 871 434	-
New share issue	6 381 099	-	46 440 397	-	-
Warrants	-	-	-28 630	-	-
Diposition according to AGM decision	-	-	-	-13 810 029	13 810 029
Profit for the year	-	-		-	-67 678 901
Total Shareholders's Equity 2023-12-31	**9 699 445**	**38 354 755**	**211 469 023**	**-108 905 340**	**-67 678 901**
Opening balance 2024-01-01	9 699 445	38 354 755	211 469 023	-108 905 340	-67 678 901
New share issue	4 392 832	-	15 221 186	-	-
Reduction of share capital	-3 730 835	-	-	3 730 835	-
Warrants	-	-	-28 630	-	-
Diposition according to AGM decision	-	-	-	-67 678 901	67 678 901
Profit for the year	-	-	-	-	-32 409 725
Total Shareholders's Equity 2024-12-31	**10 361 442**	**38 354 755**	**226 661 579**	**-172 853 406**	**-32 409 725**

Proposal for Allocation of the Company's Profit or Loss

The Board of Directors proposes that unrestricted equity, SEK 21,398,448, be appropriated so that SEK 21,398,448 is carried forward. No dividend will be paid to the shareholders.

	Amounts i SEK
Share premium account	226 661 579
Loss brought forward	-172 853 406
Profit for the year	-32 409 725
Total for the Year	**21 398 448**

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

Income Statement
GROUP

	Note	2024-01-01 2024-12-31	2023-01-01 2023-12-31
Operating Income			
Other operating income	3	50 054	902 882
		50 054	**902 882**
Operating Expenses			
Other external expenses		-29 870 408	-21 680 702
Personnel costs	4	-13 165 646	-13 740 093
Capitalized expenses for own account		28 067 172	17 192 235
Depreciation and impairment of tangible and intangible fixed assets	5	-19 184 271	-50 217 319
Other operating expenses	6	-520 599	-469 509
Operating Profit/Loss		**-34 623 698**	**-68 012 506**
Result From Financial Items			
Interest income and similar items		914 926	607 240
Interest expense and similar income and expense items	7	-641 466	-572 026
Profit After Financial Items		**-34 350 238**	**-67 977 292**
Profit Before Taxes		**-34 350 238**	**-67 977 292**
Profit for the Year		**-34 350 238**	**-67 977 292**

Balance Sheet
GROUP

	Note	2024-12-31	2023-12-31
ASSETS			
Fixed Assets			
Intangible fixed assets			
Capitalized expenditure on development, patents, licences, and trademarks	8	56 798 907	56 143 419
		56 798 907	**56 143 419**
Tangible fixed assets			
Equipment, tools and installations	9	546 409	707 510
		546 409	**707 510**
Total Fixed Assets		**57 345 316**	**56 850 929**
Current Assets			
Current receivables			
Tax receivables		126 969	
Other receivables		1 424 481	801 267
Prepayments and accrued income	11	667 634	1 683 371
		2 219 115	2 484 638
Cash and bank		**23 715 242**	**43 302 712**
Total Current Assets		**25 934 357**	**45 787 350**
TOTAL ASSETS		**83 279 673**	**102 638 279**
SHAREHOLDER'S EQUITY AND LIABLITIES			
Shareholder's Equity			
Share capital		10 361 442	9 699 445
Other contributed capital		226 661 579	211 469 023
Other equity incl. profit for the year		-169 682 900	-139 130 494
Total Equity		**67 340 121**	**82 037 974**
Non-Current Liabilities			
Liabilities to credit institutions		4 456 215	6 352 920
		4 456 215	**6 352 920**
Current Liabilities			
Liabilities to credit institutions		1 896 706	1 896 706
Advances from customers		3 552 196	8 157 140
Accounts payable		2 817 302	1 789 333
Tax liabilities		176 421	217 885
Other current liabilities		645 560	473 091
Accured expenses and deferred income		2 395 152	1 713 230
		11 483 337	**14 247 385**
TOTAL SHAREHOLDER'S EQUITY AND LIABILITIES		**83 279 673**	**102 638 279**

Cash Flow Statement
GROUP

	Note	2024-12-31	2023-12-31
Operating Activities			
Result after financial items		-34 350 238	-67 977 292
Adjustments for items not included in the cash flow, etc.		19 251 268	49 794 499
Cash Flow From Operating Activities Before Changes in Working Capital		**-15 098 970**	**-18 182 793**
Cash flow from changes in working capital			
Change in current receivables		265 523	975 403
Change in accounts payable		1 027 969	-8 542 052
Change in current liabilities		812 927	699 270
Cash Flow from Operating Activities		**-12 992 551**	**-25 050 172**
Investing Activities			
Investments in intangible assets		-24 283 602	-1 016 568
Acquisitions of tangible fixed assets		-	-758 164
Cash Flow from Investing Activities		**-24 283 602**	**-1 774 732**
Financing Activities			
Warrants		-28 630	-28 630
Rights issue		19 614 018	52 821 495
Change in loans		-	7 600 000
Repayment of loan liabilities		-1 896 705	-1 524 287
Cash Flow from Financing Activities		**17 688 683**	**58 868 578**
Cash Flow for the Year		**-19 587 470**	**32 043 674**
Cash and Cash Equivalents at Beginning of Year		**43 302 712**	**11 259 038**
Cash and Cash Equivalents at end of Year		**23 715 242**	**43 302 712**

Notes to Cash Flow Statement
GROUP

Note Other Disclosures to the Cash Flow Statement

Adjustment for Items not Included in the Cash Flow etc.	2024-12-31	2023-12-31
Depreciation and amortization	164 701	155 210
Unrealized exchange rate differences	19 019 570	50 062 109
Exchange rate differences	66 997	-422 822
	19 251 268	**49 794 499**

Investments in Intangible Aassets	2024-12-31	2023-12-31
Expenses for the year	-28 040 894	-18 581 473
Acquisition of patents	-607 142	-506 495
Activated R&D grants	8 969 378	17 875 060
Change in prepaid contributions	-4 604 944	196 340
	-24 283 602	**-1 016 568**
Prepaid grants	3 099 500	10 985 870
Tax refund attributable to accrued expenses	977 624	6 873 498
	4 077 124	**17 859 368**

Income Statement
PARENT COMPANY

	Note	2024-01-01 2024-12-31	2023-01-01 2023-12-31
Operating Income			
Net turnover	3	50 054	902 882
		50 054	**902 882**
Operating Expenses			
Other external costs		-23 287 562	-21 303 870
Personnel cost	4	-13 165 646	-13 740 093
Capitalized expenses on own account		21 725 898	17 192 235
Depreciation and impairment of tangible and intangible fixed assets	5	-13 927 894	-50 217 319
Other operating expenses	6	-520 599	-469 509
Operating Profit/Loss		**-29 125 749**	**-67 635 674**
Result From Financial Items			
Income from participations in group companies		-3 543 234	-
Interest income and similar items		900 724	528 799
Interest expenses and similar items	7	-641 466	-572 026
Profit/Loss after Financial Items		**-32 409 725**	**-67 678 901**
Profit/Loss Before Taxes		**-32 409 725**	**-67 678 901**
Net Income for the Year		**-32 409 725**	**-67 678 901**

Balance Sheet
PARENT COMPANY

	Note	2024-12-31	2023-12-31
ASSETS			
Fixed Assets			
Intangible fixed assets			
Capitalized expenditure for development work and similar work	8	45 813 113	45 209 571
		45 813 113	**45 209 571**
Tangible fixed assets			
Machinery and other technical equipment	9	546 409	707 510
		546 409	**707 510**
Financial Fixed Assets			
Shares in group companies	10	14 195 622	14 195 622
		14 195 622	**14 195 622**
Total Fixed Assets		**60 555 144**	**60 112 703**
Current Assets			
Current receivables			
Other receivables		1 424 512	652 100
Prepaid expenses and accrued income	11	**667 634**	**455 266**
		2 092 146	**1 107 366**
Cash and bank		23 189 838	42 001 609
Total Current Assets		**25 281 984**	**43 108 975**
TOTAL ASSETS		**85 837 128**	**103 221 678**
SHAREHOLDER'S EQUITY AND LIABILITIES			
Shareholder's Equity			
Restricted equity			
Share capital		10 361 442	9 699 445
Fund for development expenditure		38 354 755	38 354 756
		48 716 197	**48 054 201**
Unrestricted equity			
Share premium reserve		226 661 579	211 469 023
Retained earnings		-172 853 406	-108 905 341
Result for the year		-32 409 725	-67 678 901
		21 398 448	**34 884 781**
Total Shareholder's Equity		**70 114 645**	**82 938 982**
Long-Term Liabilities			
Other liabilities to credit institutions	12	4 456 215	6 352 920
		4 456 215	**6 352 920**
Current Liabilities			
Liabilities to credit institutions		1 896 706	1 896 706
Advances from customers		3 552 196	8 157 140
Accounts payable to suppliers		2 600 234	1 471 725
Tax liabilities		176 421	217 885
Other current liabilities		645 560	473 091
Accrued expenses and deferred income	13	2 395 151	1 713 229
		11 266 268	**13 929 776**
TOTAL SHAREHOLDER'S EQUITY AND LIABILITIES		**85 837 128**	**103 221 678**

Cash Flow Statement
PARENT COMPANY

	Note	2024-12-31	2023-12-31
Cash Flow From Operations			
Result after financial items		-32 409 725	-67 678 901
Adjustment for non-cash items		17 471 128	50 217 319
		-14 938 597	-17 461 582
Cash Flow from Operations Before Changes in Working Capital		**-14 938 597**	**-17 461 582**
Changes in Working Capital			
Change in current receivables		-984 780	-127 342
Change in accounts payable		1 128 509	-92 835
Change in current liabilities		812 927	699 270
Cash Flow from Operating Activities		**-13 981 941**	**-16 982 489**
Investing Activities			
Shareholders' contributions paid		-3 543 234	-2 874 782
Investments in intangible assets		-18 975 279	-6 500 828
Investment in tangible fixed assets		-	-758 164
Cash flow from investing activities		**-22 518 513**	**-10 133 774**
Financing Activities			
New share issue		19 614 018	52 821 496
Warrants		-28 630	-28 630
Loans raised		-	7 600 000
Repayment of loans		-1 896 705	-1 524 287
Cash Flow From Financing Activities		**17 688 683**	**58 868 579**
Cash Flow for the Year		**-18 811 771**	**31 752 316**
Cash and Cash Equivalents at the Beginning of the Year		**42 001 609**	**10 249 293**
Cash and Cash Equivalents at the end of the Year		**23 189 838**	**42 001 609**

Notes to Cash Flow Statement
PARENT COMPANY

Note Other Disclosures to the Cash Flow Statement

Adjustment for Items not Included in the Cash Flow etc.	2024-12-31	2023-12-31
Depreciation	164 701	155 210
Impairment losses/reversal of impairment losses	17 306 427	50 062 109
	17 471 128	**50 217 319**

Investments Intangible Assets	2024-12-31	2023-12-31
Expenses for the year	-21 754 947	-17 192 235
Acquired patents	-607 142	-506 495
Activated R&D grants	7 991 754	11 001 562
Prepaid grants	-4 604 944	196 340
	-18 975 279	**-6 500 828**
Contributions Paid	3 099 500	10 985 870

Notes

Note 1 Accounting Principles

Amounts in SEK unless otherwise stated.

General Accounting Principles

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

Consolidated Acounts

Subsidiaries

Subsidiaries are companies in which the parent company directly or indirectly holds more than 50% of the voting rights or otherwise has a controlling influence.

Valuation Principles, etc.

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

Government Grants

The public grants that are not linked to future performance requirements are recognized as revenue when the conditions for receiving the grant are met. The public grants that we have and are subject to future performance requirements are amortized over the period to which they relate and reduce the value of the intangible asset.

Intangible Assets

Research and Development Expenditure

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

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

Tangible Fxed Assets

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

Amortization

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

	Group %	Parent Company %
Patent	12,5	12,5
Equipment, tools and installations	20	20

Testing for Impairment of Intangible and Tangible Assets

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

Leasing - Lessees

All leases have been classified as finance or operating leases.

Operating Leases

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

Foreign Currency

Foreign Currency Items

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

Cash Flow Statement

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

The entity classifies bank balances as cash and cash equivalents.

Equity Capital

Equity of the enterprise consists of the following items:

- Share capital representing the nominal value of issued and registered shares.
- share premium account, which includes any premium received on the issue of new share capital.
  Any transaction costs associated with the issue of new shares are deducted from the share premium account, taking into account any income tax effects.
- The development expenditure fund is increased annually by the amount capitalized in respect of the company's own development work. The fund is reduced annually by the amortization of the capitalized development work.
- Retained Earnings/Accumulated Loss and Net Profit for the Year, i.e. all retained earnings and share-based payments for the current and prior periods, as well as acquisitions of own shares.
- In the Group's equity, other contributed capital is share premium account.
- Other equity is the fund for development expenditure, retained earnings and profit for the year.

Note 2 Estimates and Judgments

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

Significant Judgments

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

Capitalization of Intangible Assets

To assess any impairment of the intangible asset, a recoverable amount is calculated based on the expected future cash flow with an expected start of sales in 2027. We have also calculated an appropriate discount rate (WACC) based on market conditions and by comparing with peer companies, to discount the cash flow. In the calculation of the recoverable amount. In this assessment, which extends a number of years into the future (up to 2034), there are uncertainties about future cash flows and the appropriate discount rate. The sales price we have assigned to the product is in line with the only similar product currently on the market but which, in our assessment, is based on old technology and cannot really be compared with our product in terms of user-friendliness, reliability and mobility.

Our assessment is based on available information and is based on our plan for commercialization. The risks we assess are if there would be delays in approvals from medical authorities in the EU and the US and thus our own commercialization process.

Note 3 Other Operating Income

	2024-01-01 2024-12-31	2023-01-01 2023-12-31
GROUP		
Exchange rate gains on operating receivables/liabilities	48 124	38 795
Sick pay	-	864 149
Refund of surplus from insurance companies	-	-
Others	1 930	-62
Total	**50 054**	**902 882**
PARENT COMPANY		
Exchange gains on operating receivables/liabilities	48 124	38 795
Grants received	-	864 149
Sick pay	-	-
Others	1 930	-62
Total	**50 054**	**902 882**

Note 4 Employees, Staff Costs and Directors' Fees

Average Number of Employees

PARENT COMPANY	2024-01-01 2024-12-31	Of which men	2023-01-01 2023-12-31	Of which men men
Sweden	12	9	13	10
Total Parent Company	12	9	13	10
Of Wich CEO	1		1	
Of which board members				
SUBSIDIARY				
Australia				
Total Group	**12**	**9**	**13**	**10**

Salaries and Other Remuneration Broken Down by Country and Between Directors etc. and Other Employees	**2024-01-01** **2024-12-31** Board and Management	**2024-01-01** **2024-12-31** Others employees	**2023-01-01** **2023-12-31** Board and Management	**2023-01-01** **2023-12-31** Others employees
PARENT COMPANY				
Sweden	3 144 848	5 778 511	3 115 073	6 419 208
Of Wich CEO	1 279 603	-	1 278 603	-
Of which management exclusive CEO	1 214 546	-	1 256 874	-
Of which board fees	650 599	-	579 596	-
Total Parent Company	**3 144 848**	**5 778 511**	**3 115 073**	**6 419 208**
SUBSIDIARY				
Australia	-	-	-	-
Total Subsidiary	-	-	-	-
Total Group	**3 144 848**	**5 778 511**	**3 115 073**	**6 419 208**

Social security costs SEK 3,182,328 (4,594,085) of which pension costs SEK 1,806,841 (1,716,564).

Distribution of Directors' Fees	**2023**	**2024**
Ulf Grape	62 500	31 250
Christer Norström (Chairman)	150 000	75 000
Solveig Bergström	62 500	70 000
Oliver Voigt	62 500	70 000
Azad Najar	62 500	70 000
Stuart McConchie	27 213	65 963
Giovanni Lauricella	12 088	68 970
Magnus Öhman (Chairman)	40 058	160 116
	479 359	**611 299**

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

	2024-01-01 2024-12-31	2023-01-01 2023-12-31
GROUP		
Depreciation according to plan broken down by asset		
Concessions, patents, licenses, trademarks	3 600	58 488
Equipment, tools and installations	161 101	96 722
	164 701	**155 210**
Impairment losses broken down by asset:		
Capitalized expenditure on research and development and similar activities	19 019 570	50 062 109
	19 019 570	**50 062 109**
	19 184 271	**50 217 319**
PARENT COMPANY		
Depreciation according to plan broken down by asset		
Concessions, patents, licenses, trademarks	3 600	58 488
Equipment, tools and installations	161 101	96 722
	164 701	**155 210**
Impairment losses broken down by asset:		
Capitalized expenditure on research and development and similar activities	13 763 193	50 062 109
	13 763 193	**50 062 109**
Summa	**13 927 894**	**50 217 319**

Note 6 Other Operating Expenses

	2024-01-01 2024-12-31	2023-01-01 2023-12-31
GROUP		
Exchange losses on operating receivables/liabilities	159 814	234 977
Exchange rate difference	360 785	234 532
Total	**520 599**	**469 509**
PARENT COMPANY		
Exchange losses on operating receivables/liabilities	159 814	234 977
Exchange rate difference	360 785	234 532
Total	**520 599**	**469 509**

Note 7 Interest Expense and Similar Items

	2024-01-01 2024-12-31	2023-01-01 2023-12-31
GROUP		
Interest expense	636 770	570 891
Interest expense, accounts payable	606	546
Interest expense for taxes and duties	4 090	589
Total	**641 466**	**572 026**
PARENT COMPANY		
Interest expense	636 770	570 891
Interest expense, accounts payable	606	546
Interest expense for taxes and duties	4 090	589
Total	**641 466**	**572 026**

Note 8 Capitalized Expenditure for Development Work

GROUP	2024-12-31	2023-12-31
Accumulated acquisition values:		
-At the beginning of the year, development work	128 208 760	109 627 288
-New acquisitions	28 073 398	18 581 472
-Translation differences for the year	-22 797	682 828
-Development Work at the End of the Year	**156 282 158**	**128 208 760**
-Activated R&D grants at the beginning of the year	-18 347 030	-7 345 468
-Activated R&D grants	-7 991 754	-11 001 562
-Activated R&D Grants at the End of the Year	**-26 338 784**	**-18 347 030**
-Capitalized tax refund development costs at beginning of year	-6 873 498	-
-Capitalized tax refund for the period	-994 443	-7 099 158
-Translation differences for the year	-15 781	225 660
-Capitalized tax Refund Development Costs at the End of the Year	**-7 883 722**	**-6 873 498**
-Patents at the beginning of the year	7 308 982	6 802 488
-New acquisitions	607 141	506 495
-Patent at the end of the year	7 916 123	7 308 983
Accumulated Acquisition Values	**129 975 775**	**110 297 215**
Accumulated depreciation and impairment losses		
-Write-down of capitalized expenditure at beginning of year	-53 699 630	-3 637 521
-Depreciation for the year*	-19 019 472	-50 062 109
-Depreciation of Capitalized Expenditure at the End of the Year	**-72 719 102**	**-53 699 630**
-Amortization of patents at beginning of the year	-454 166	-395 678
-Depreciation for the year	-3 600	-58 488
-Amortization of patents at end of the year	-457 766	-454 166
Accumulated Depreciation and Impairment Losses	**-73 176 868**	**-54 153 796**
Carrying Amount at the End of the Year	**56 798 907**	**56 143 419**

PARENT COMPANY		
Accumulated acquisition values:	56 798 907	56 143 419
-At the beginning of the year, development work	110 401 414	93 209 180
-New acquisitions	21 754 949	17 192 234
-Development Work at the End of the Year	**132 156 363**	**110 401 414**
-Activated R&D grants at the beginning of the year	-18 347 030	-7 345 468
-Activated R&D grants	-7 991 754	-11 001 562
-Capitalized Contributions at the End of the Year	**-26 338 784**	**-18 347 030**
-Patents at the beginning of the year	7 308 982	6 802 488
-New acquisitions	607 141	506 495
-Patents at the end of the year	7 916 123	7 308 983
Accumulated Acquisition Values	**113 733 702**	**99 363 367**
Accumulated amortization and impairment losses:		
-Amortization at beginning of year, capitalized expenditure	-53 699 630	-3 637 521
-Depreciation for the year	-13 763 193	-50 062 109
-Impairment Losses on Capitalized Expenditure at the End of the Year	**-67 462 823**	**-53 699 630**
-Amortization of patents at beginning of year	-454 166	-395 678
-Depreciation for the year	-3 600	-58 488
-Amortization of patents for the year	-457 766	-454 166
Accumulated Depreciation and Impairment Losses	**-67 920 589**	**-54 153 796**
Carrying Amount at the End of the Year	**45 813 113**	**45 209 571**

Note 9 Machinery and Other Technical Installations

GROUP	**2024-12-31**	**2023-12-31**
Accumulated acquisition values		
-At the beginning of the year (Parent Company)	1 598 473	840 309
-New acquisitions	-	758 164
-At the end of the year	1 598 473	1 598 473
Accumulated amortization		
-At the beginning of the year	-890 963	-794 241
-Depreciation for the year	-161 101	-96 722
-At the end of the year	-1 052 064	-890 963
Carrying Amount at the End of the Year	**546 409**	**707 510**
PARENT COMPANY		
Accumulated acquisition values		
-At the beginning of the year	1 598 473	840 309
-New acquisitions	-	758 164
-At the end of the year	1 598 473	1 598 473
Accumulated amortization		
-At the beginning of the year	-890 963	-794 241
-Depreciation for the year	-161 101	-96 722
-At the end of the year	-1 052 064	-890 963
Carrying Amount at the End of the Year	**546 409**	**707 510**

Note 10 Shares in Group Companies

	2024-12-31	2023-12-31
Accumulated acquisition cost:		
-Company formation	78	78
-Shareholder contributions	14 195 544	11 320 840
-At the Beginning of the Year	**14 195 622**	**11 320 918**
-Shareholders' contributions for the year	3 543 234	2 874 704
-Impairment for the year	-3 543 234	-
Carrying Amount at the End of the Year	**14 195 622**	**14 195 622**

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

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

Subsidiary / Org nr / Registered Office	Number of Shares in %	Carrying Amount
Scandinavian Realheart Pty,orgnr 629 303 788 Victoria, Austalien	100	14 195 622

Note 11 Prepaid Expenses and Accrued Income

	2024-12-31	2023-12-31
GROUP		
Prepaid rent	141 434	127 877
Prepaid leasing fees	-	70 000
Prepaid insurance	9 771	9 648
Prepaid costs Hydrix	-	1 228 105
Other interim charges	516 429	247 741
	667 634	**1 683 371**
PARENT COMPANY		
Prepaid rent	141 434	127 877
Prepaid leasing fees	-	70 000
Prepaid insurance	9 771	9 648
Other interim charges	516 429	247 741
	667 634	**455 266**

Note 12 Other Liabilities to Credit Institutions

	2024-12-31	2023-12-31
GROUP		
Maturity date, within one year of the balance sheet date	1 896 706	-
Maturity date, 2-5 years from balance sheet date	2 559 509	6 034 023
Maturity date, later than five years from the balance sheet date	-	318 897
	4 456 215	**6 352 920**
PARENT COMPANY		
Maturity date, within one year of the balance sheet date	1 896 706	-
Maturity date, 2-5 years from balance sheet date	2 559 509	6 034 023
Maturity date, later than five years from the balance sheet date	-	318 897
	4 456 215	**6 352 920**

Note 13 Accrued Expenses and Deferred Income

	2024-12-31	2023-12-31
GROUP		
Accrued vacation pay	948 397	1 133 215
Social security holiday pay liability	281 532	349 075
Other items	1 165 223	230 940
	2 395 152	**1 713 230**
PARENT COMPANY		
Accrued vacation pay	948 397	1 133 215
Social security holiday pay liability	281 532	349 075
Other items	1 165 222	230 939
	2 395 151	**1 713 229**

Note 14 Pledged Assets and Contingent Liabilities Group

	2024-12-31	2023-12-31
Collateral Pledged		
GROUP		
Company mortgages	10 000 000	10 000 000
Total Collateral Pledged Group	**10 000 000**	**10 000 000**
PARENT COMPANY		
Company mortgages	10 000 000	10 000 000
Total Collateral Pledged Parent Company	**10 000 000**	**10 000 000**

Note 15 Significant Events After the end of the Financial Year

Research and Development Activities

The company's total artificial heart, Realheart® TAH, has been granted Humanitarian Use Device (HUD) designation by the US Food and Drug Administration (FDA). The HUD designation makes Realheart® TAH eligible to apply for Humanitarian Device Exemption (HDE), an expedited regulatory pathway that can grant the product special market rights.

During the month of January, Realheart has achieved successful results from a completed 7-day animal study with Realheart® TAH. The results show that the device provides adequate cardiac function, automatically adapts to rest and exercise, and maintains good blood biochemistry.

In April, Realheart was granted a patent approval by the Japan Patent Office (JPO) for a pressure sensor for artificial hearts and circulatory support systems such as Realheart® TAH. The patent is a supporting measure to ensure market protection for the company's device in the Japanese market and is valid until 2041.

Financing

During the month of February, the outcome of the subscription period for the warrants of series TO2 (Warrants) issued in connection with the rights issue of units carried out by the Company during the period June 20, 2023 - July 7, 2023 will be announced. A total of 17,035,600 Warrants were exercised for subscription of 85,178 shares, corresponding to a subscription rate of approximately 51 percent of the total 33,495,885 issued Warrants. Through the exercise, Realheart will receive approximately SEK 721 thousand before issue costs.

In April, Realheart announces the outcome of the subscription period for the warrants of series TO 3 ("Warrants") issued in connection with the rights issue of units carried out by the Company during the period June 12, 2024 - July 5, 2024. In total, 31,998,400 Warrants were exercised for subscription of 159,992 shares, corresponding to a subscription rate of approximately 58 percent of the total 54,910,406 Warrants issued. Through the exercise, Realheart will receive approximately SEK 2.1 million before issue costs.

In March, the Board of Directors decided to carry out a directed share issue of a maximum of 2,881,115 shares at a subscription price of SEK 11.31 per share. The investors in the directed share issue consist of a limited number of qualified and other professional investors, including both new and existing shareholders, including the European Investment Council, Claes Mellgren and Per Olof Andersson. During April and May, a total of 2,685,382 shares were subscribed for, raising SEK 30.4 million before transaction costs.

Note 16 Key Figure Definitions

Balance sheet total
Total assets.

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

Cash liquidity:
Current assets excluding inventories and work in progress/current liabilities.

Signatures

Västerås, 2025-05-22

Magnus Öhman
Chairman of the Board of Directors

Ina Laura Perkins
Chief Executive Officer

Oliver Voigt
Member of the Board of Directors

Giovanni Laruricella
Member of the Board of Directors

Azad Najar
Member of the Board of Directors

Stuart McConchie
Member of the Board of Directors

Solveig Bergström
Member of the Board of Directors

Our audit report was submitted on 2025-05-22

Grant Thornton Sweden AB

Joakim Söderin
Authorized Public Accountant

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

Auditor's Report

N.B. The English text is a translation of the official version in Swedish. In the event of any conflict between the Swedish and English version, the Swedish shall prevail.

To the general meeting of the shareholders of Scandinavian Real Heart AB

Corporate identity number 556729 - 5588

Report on the Annual Accounts and Consolidated Accounts

Opinions
We have audited the annual accounts and consolidated accounts of Scandinavian Real Heart AB for the year 2024.

In our opinion, the annual accounts and consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and the group as of 31 December 2024 and their financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts. We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Basis for Opinions
We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

Emphasis of Matter
Without prejudice to our statements above, we would like to draw attention to the description in the annual report (note 2, page 43) under the heading Capitalization of intangible assets, which states that the value of the intangible asset is based on the assumption that the product will be fully developed and commercialized.

Other Information Than the Annual Accounts and Consolidated Accounts
On the company's website, there is a published annual report and consolidated financial statements in English (this report), which is a translation of the original document. This report also contains other information than the annual report and consolidated financial statements which can be found on pages 5 - 27. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Directors and the Managing Director
The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

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

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

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consoli-dated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report.

However, future events or conditions may cause a company and a group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Plan and perform the group audit to obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business units within the group as a basis for forming an opinion on the consolidated accounts. We are responsible for the direction, supervision and review of the audit work performed for purposes of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

Report on Other Legal and Regulatory Requirements

Opinions
In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Scandinavian Real Heart AB for the year 2024 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Basis for Opinions
We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

Responsibilities of the Board of Directors and the Managing-Director
The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's Responsibility
Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Stockholm, according to the date indicated by the electronic signature.
Grant Thornton Sweden AB

Joakim Söderin
Authorised Public Accountant

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