



Interim Report 220101-220630

Press Release 19 August, 2022

Summary of Interim Report

First to Second Quarter 2022 (2022-01-01 – 2022-06-30)

- Operating income amounted to 903 789 (528 702) SEK.
- Earnings after financial items amounted to - 5 911 082 (-4 008 690) SEK.
- Earnings per share * amounted to SEK -0.18 (-0.18).
- Equity / assets ratio was 93% (83%).

Second Quarter 2022 (2022-04-01 – 2022-06-30)

- Operating income amounted to 685 380 (527 625) SEK.
- Earnings after financial items amounted to - 3 209 011 (-2 229 708) SEK.
- Earnings per share * amounted to SEK – 0.10 (-0.10).

* *Earnings per share: Earnings for the period divided by 33 183 461.*

** *Equity ratio: Equity divided by total capital.*

Amounts in parentheses refer to the corresponding period last year.

Significant Events During the Second Quarter of the Year

- At the beginning of April, Realheart starts collaborations with researchers with expert knowledge about heart pumps, at KTH in Stockholm. The collaborations add to the company additional expertise in the areas of blood testing and evaluation of the control unit to the clinical version of Realheart® TAH, as well as in the company's research on new products.
- In mid-April, the clinical version will be announced of Realheart's artificial heart - the one to be used by human patients - is almost finished and will now be tested in a serie of animal experiments. Six surgeries are booked, with the first operation already in mid-May.
- At the end of April, Realheart begins the recruitment of a new Chief Financial Officer to take over when the current CFO Andreas Hultdin ends July 31.
- Improved control unit for clinical studies provides six months delay, the company announced at the end of April.

The delay is due to the decision of giving the patients in the first clinical study the chance to be equipped with the final version of the control unit - a kind of remote control - instead of a simpler version as previously thought.

- On May 1, a layout version of the annual report for 2021, is released, including reportage with Dr Dilek Gürsoy.

- May also begins with Realheart being granted additional funding for two US patents until 2037, including one that protects the principle behind the four-chamber heart in its entirety.

- During the second week of May, the recruitment of a Lead

Systems Engineer is completed. Bruce Wedding from Texas, comes recently from a role as a senior software engineer at LivaNova, PLC.

- In mid-May, the company announces that the first try of clinical implantation is postponed due to the change of animals.

- One of the last events in May is that Realheart and KTH receives a grant of SEK 4 million from Vinnova to jointly develop a Swedish hybrid simulator that should enable advanced testing of the control algorithm which governs Realheart's artificial heart.

- May also ends with Realheart's CEO Ina Laura Perkins presenting Realheart® TAH blood results at the International EUMS-ISMCS Conference in Hanover.

- In connection with the ISMCS conference it is announced that Ina Laura Perkins has been elected to the Board of International Society for Mechanical Circulatory Support (ISMCS).

- The first event in June is that the first implantation with the clinical version is performed on animals. Surgically, the experiment is very successful and the pump performs optimally. The surgical team implants the pump in only 2 hours and 10 minutes - a key factor in the animal's survival.

Significant Events After the End of the Period

- July begins with the second successful implantation of the clinical version in animals. The animal survives for 24 hours, which is an important milestone for the company.

Revenue and Result

Scandinavian Real Heart is currently working with research and development and currently has no sales of any products. The turnover reported for the period consists of grants received. Research and development costs of Realheart® TAH were capitalized during Q2 with 8.2 million. During the period, write-downs of capitalized costs for research and development were made by 0 million.

The item other external costs of 9.6 million consists of costs for purchased services of 6.3 million and various other costs of SEK 3.3 million. Of these costs, 6.6 million has been capitalized.

Financial Position

Following the rights issue completed in 2021, the Company is now in a strong liquidity position with approx. SEK 24 million in liquid funds. Together with the grant of SEK 25.7 million that we have been granted from the EIC and which we will receive in 2022/2023, we have funding that will last into quarter 2, 2023.

In order to solve the Company's longer-term financing needs, Realheart works continuously to evaluate alternatives for further capitalization of the Company. One possibility is to be able to

finance the Company in the future via equity from financially strong additional owners as well as from other sources such as EU support and non-profit foundations.

CEO Ina Laura Perkins has the word

In June, we started our animal studies with the clinical version of Realheart® TAH! For this series, we have a strengthened surgical team as well as new expertise in aftercare and an enhanced aftercare protocol. A heart replacement is among the largest surgical procedures that can be performed, and while a human patient is kept sedated for the first critical day, a sheep must be awakened shortly afterwards, making aftercare particularly complex. There are many things we want to confirm during each operation - from ease of use from the surgeons' perspective to a stable and controlled transition from the heart-lung machine. The smooth implantation of the Realheart® TAH resulted in a relatively short total time on the heart-lung machine - something that is of great importance for survival and really impressed everyone involved. The performance of the pump also impressed. Now we continue with high expectations for future operations.

We have also started our virtual study this spring. Using three-dimensional digital replicas of real heart patients, we can test how our product fits in different bodies, among other things. We have already performed implantations on ten virtual patients and our artificial heart fit all eight male patients, but not the two female ones. The study will continue with at least twenty more patients and can be further expanded, if we need more data. Through these studies, we are collecting anatomical measurements to define the patient population for the application to start clinical trials, but also for our other product MiniHeart, which is being developed for women and other patients with smaller body sizes.

At the same time, we are continuing to work on our blood tests, a key part of the development process, as we want to move away from the blood-related side effects that have so far limited the use of artificial hearts. In addition, to enter clinical trials, it is a requirement to show that haemolysis - the leakage of haemoglobin from red blood cells - is at least as low as in a product in clinical use. We are comparing with SynCardia, the most widely used artificial heart on the market, and in tests with the previous version of Realheart we got very good results that were far below SynCardia's. Soon we will start tests with our clinical version, where we hope to get even lower.

Many people follow our work with interest and anticipation, and it was against this background that the European Mechanical Circulatory Support Summit (EUMS) and the International Society for Mechanical Circulatory Support (ISMCS) asked me to present our blood results at their joint conference in Hannover. While there, I received a lot of feedback from physicians who are frustrated by the lack of a good TAH. International physicians are increasing amongst our social media followers, and since that conference we have received an offer of help in future clinical trials from physicians in the US.

We recently hosted an international conference ourselves to disseminate the research results generated within the company and among our partners. The dream would be to welcome the ISMCS conference to Sweden sometime in the future, now that I have been elected to the board, and described as "a bridge between research and industry"!

What we do is ground-breaking, and our collective expertise continues to grow. Oliver Voigt, who started working with us as a consultant last year, has now taken a seat on our board. He was previously General Manager of SynCardia in Europe and led their expansion from two to 26 countries. Greater knowledge of marketing and selling artificial hearts is not to be found anywhere in the world. The Board has also gained two additional new members with valuable experience: Patrick Schnegelsberg, who among other things, has been CEO of medtech and biotech start-ups and has led ten heart-related products to market approval; and Solveig Bergström, who has led companies from start-up to establishment of international subsidiaries, acquisitions and sales for 30 years.

In addition, we are supported by seven cardiac surgeons, who help us in various ways to drive the project forward: Henrik Ahn, Robert Dowling, and Ulf Kjellman, who contribute to the

planning and preparations towards clinical trials; Jan Schmitto, who has given us access to patients for the virtual study; and Dilek Gürsoy, Bart Meyns and Joeri van Puyvelde, who are at the operating table in our animal studies. Having access to their expertise is invaluable, and the fact that they believe so strongly in our product gives us extra confidence.

Ina Laura Perkins

CEO, Scandinavian Real Heart AB

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 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 granted patents in Sweden, Germany, the United Kingdom, the United States, China and India that protect the original pump principle in TAH. This patent also provides protection for future products: RealVAD® and PulsePump®.

Patent protection is also available on the latest version of Realheart® TAH in Sweden, USA, UK, Australia and Japan. The patent application for it has also been filed for Germany and Canada. The patents provide protection in the markets that are largest and most important for artificial hearts right now, with the exception of China and India which are considered important emerging markets. In addition to the patent protection described above, Realheart has also approved patents in Sweden, the USA and the United Kingdom for the future Sternal prosthesis product. The application is also submitted in Germany and France. In 2018, a new connection was designed for a simple and secure connection between Realheart® TAH and the body's circulatory system. The patent application for this has also been filed.

Finally, the patent application has been filed in two parts for the use of pressure sensors for the automatic control. Given the existing patents together with the new patent applications, the Board 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

Scandinavian Real Heart AB was listed on the 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 gain access to growth capital to develop and expand their operations. As of December 31, 2021, the number of shares in Scandinavian Real Heart was 33,183,461.

Largest Shareholder in the Company per 2022-06-30

Shareholders Capital (%)	Numbers of Shares	Votes (%)
Najar Medical & Invention AB 9,83	3 262 635	9,83
Eskilstunahem Fastighets AB 4,97	1 650 006	4,97
Försäkrings AB Avanza 4,44	1 471 845	4,44
Ålandsbanken ABP (finland) Swedish branch 2,57	852 181	2,57
Najar Bilend 1,56	516 263	1,56
Forslund Lars 1,48	489 474	1,48
Nordnet Pensionsförsäkring AB 1,40	464 334	1,40
Smartgroup Holding AB 1,26	417 316	1,26
Staffan Ewerth 1,05	350 000	1,05
Gilbert Raux 0,92	306 500	0,92
Others 70,52	23 402 907	70,52
Total 100,00	33 183 461	100,00

Principles for the Preparation of the Interim Report

The interim report has been prepared in accordance with the Annual Accounts Act and with the application of general advice, recommendations and statements from the Swedish Accounting Standards Board.

Audit Review

The interim report has not been reviewed by the Company's auditor.

Upcoming Financial Reports

Interim Report Q3, 2022 2022-11-18

Year-end Report, 2022 2023-02-24

Submission of Interim Report

Västerås, August 19, 2022

The Board

Scandinavian Real Heart AB

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This disclosure contains information that Real Heart is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information in this press release has been published through the agency of the contact persons set out below, at the time stated by Scandinavian Real Heart AB's news distributor Cision upon publication of this press release.

Link to archive for financial reports: <https://realheart.se/sv/investerare/arkiv/>

Scandinavian Real Heart AB develops a total artificial heart (TAH) for implantation in patients with life-threatening heart failure. Realheart® TAH has a unique, patented design that resembles that of the natural human heart. The artificial heart consists of a four-chamber system (two atria and two ventricles) designed to generate a physiological blood flow pattern that mimics the body's natural circulation. A unique concept in the medical technology world.