



## Interim Report 230701-230930

Press Release November 16, 2023

### Summary of Interim Report

	(SEK)			
Group Overview	2023-07-01	2022-01-01	2023-01-01	2022-01-01
	2023-09-30	2022-09-30	2023-09-30	2022-12-31
	3 mon	9 mon	9 mon	12 mon
Operating income	878	636 121	104 835	667 589
Earnings after financial items	-8 016 849	-10 972 419	-15 081 319	-13 987 911
Balance Sheet total	150 142 414	117 332 695	150 142 414	119 816 255
Equity / Assets ratio	90%	86%	90%	81%
Earnings per share	-0.08	-0.33	-0.16	-0.42
Number of shares	96 994 446	33 183 461	96 994 446	33 183 461
<b>Parent Company Overview</b>	<b>2023-07-01</b>	<b>2022-07-01</b>	<b>2023-01-01</b>	<b>2022-01-01</b>
	<b>2023-09-30</b>	<b>2022-09-30</b>	<b>2023-09-30</b>	<b>2022-12-31</b>
	<b>3 mon</b>	<b>3 mon</b>	<b>9 mon</b>	<b>12 mon</b>
Operating income	878	581 540	104 835	667 589
Earnings after financial items	-8 064 889	-4 224 953	-14 813 578	-13 810 029
Balance Sheet total	148 435 929	116 441 628	148 435 929	111 229 225
Equity / Assets ratio	92%	86%	92%	88%
Earnings per share	-0.08	-0.13	-0.15	-0.42
Number of shares	96 994 446	33 183 461	96 994 446	33 183 461

### Revenue and Result

Scandinavian Real Heart AB is working with research and development and currently has no sales of any products. The income reported for the period consists mainly of foreign currency exchange gains. Research and development costs of Realheart® TAH were capitalized during Q3 with 4.2 MSEK. 1.9 MSEK for purchased services and other external costs and 2.3 MSEK for personnel. During the period, write-downs of capitalized costs for research and development were made by 0 MSEK.

Other external costs of 8.9 MSEK includes cost for guarantors of 3.4 MSEK and issuing costs of 2.3 MSEK.

### Financial Position

During the period, the company has received cash of 42.2 MSEK after issuing costs from a preferred and directed share issue, 7.2 MSEK from R&D Tax credit in Australia and 0.5 MSEK

from received Grants. With a cash balance of 44 MSEK at the end of the period the company has funding that will last into the third quarter of 2024.

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

### **Significant Events During the Second Quarter of the Year**

**The period begins with** Realheart initiating a collaboration with Chief Physician and Professor Göran Dellgren at the Transplantation Centre and Thorax Clinic at Sahlgrenska University Hospital in Gothenburg. The collaboration is part of the preparations for the clinical studies with the company's artificial heart.

**During the first week of July**, it was announced that Realheart, after Almi's evaluation, has received business development support totalling SEK 0.850 million. Realheart submitted four applications, all of which have now been approved.

**Halfway through July**, Realheart publishes the outcome of the company's rights issue. A total of 21,214,649 units were subscribed, corresponding to 60.6 per cent of the Rights Issue. The Rights Issue provides the Company with approximately SEK 33.9 million before issue costs.

**The last days of July**, Realheart communicates that it carries out a directed new issue of units to guarantors in connection with the completed rights issue. The decision means that it issues 642,950 units as guarantee compensation directed to a number of the guarantors who provided guarantee commitments in the rights issue of units that the Company carried out during the period 20 June to 7 July 2023, in accordance with the guarantee agreements entered into.

**On the same day**, the company also announces that it carries out a directed issue to EIC in connection with the completed rights issue. The Company's Board of Directors, pursuant to the authorisation granted by the Annual General Meeting on 14 June 2023, decided to issue 9,150,000 units to the European Innovation Council ("EIC") Accelerator, in accordance with the investment agreement published on 15 May 2023. Realheart thus receives an additional SEK 14,640,000 before transaction costs.

**During the first part of August**, Realheart announces that the Nomination Committee of the company proposes that Magnus Öhman be elected to the Board at the next general meeting. Until then, he is co-opted to the board. Magnus Öhman has extensive experience from the medical technology industry, including as CEO of St Jude Medical's Swedish subsidiary within Cardiac Rhythm Management.

**In the second half of August**, the company announced three upcoming presentations regarding different parts of the achieved research results. The presentations take place at three different scientific conferences in Europe - ESAO in Bergamo, BDW in Rostock and EUMS in Paris - where many future customers and partners participate. Among other things, the company highlights its experience with animal-free methods in its development work and challenges the industry to take the step away from animals.

**In a press release at the end of August**, Realheart announced that CEO Ina Laura Perkins has been invited to speak about the company's artificial heart at the China Heart Congress in Beijing in September 2023. The conference is one of the largest in cardiovascular diseases in the Asia-Pacific region with over 8,000 participants. Ina Laura Perkins has been invited by one of China's leading heart surgeons, Mr Shenshou Hu, President of Fuwai Hospital in Beijing.

**The last thing that happens in August** is that Realheart decides to co-opt Stuart McConchie to the board, after the nomination committee informs that it intends to propose him as a new board member at the next general meeting. Stuart McConchie has held top positions in global medical technology companies for more than 25 years, guiding companies from research to product commercialisation.

**September begins with** the news that Realheart has been selected for Business Sweden's scale-up programme Catalyst, which aims to create international growth. In the programme, which is aimed at Sweden's most innovative and promising companies, participants receive a tailored project plan for market entry valued at SEK 250,000 and opportunities to build networks in the market, among investors and other experts.

### **Significant Events After the End of the Period**

**On the penultimate day of October**, Realheart announces another addition to the board, Giovanni Lauricella, after the nomination committee announced that it intends to propose him as a new board member at the next general meeting. Giovanni Lauricella is currently Managing Partner at Lifeblood Inc, a company specialising in recruitment and fundraising for medical device companies.

**November begins with** the press release announcing that Realheart has successfully established a new test model for evaluating the impact of artificial hearts on the blood. Initial test results show that the company's artificial heart, Realheart TAH, induces 80% lower degree of haemolysis compared to today's market-dominant heart pump system. The company will shortly start haemolysis testing with the clinical version of the product.

**In mid-November**, Realheart provides an update on the development and commercialisation of Realheart TAH based on a thorough analysis conducted under the guidance of the company's Board of Directors, including the new co-opted members. Realheart will focus more clearly on the use of the product as a bridging treatment before organ transplantation and now assesses that the product can receive reimbursement in the US already when used in clinical trials.

### **CEO Ina Laura Perkins Has the Word**

**Since last summer, we have been able to attract three new people who will be proposed for election to the Board at an Extraordinary General Meeting on November 24. They have already contributed significant knowledge and experience from the cardiac medical device industry as adjunct members. After the end of the reporting period, we could announce that initial tests show that Realheart TAH induces 80% less hemolysis than today's market-dominant artificial heart, and a few days ago we presented an updated development and commercialization plan. Although our timetable has been slightly postponed, we now see an opportunity for revenue already during the upcoming clinical trials.**

### **New Specialist Expertise to the Board**

In August, Magnus Öhman, former CEO of Cardiac Rhythm Management, and Stuart McConchie, with a background as CEO and COO of three international heart pump companies, were added to the company's board. At the end of October, Giovanni Lauricella, who has a solid network among international specialist investors, was also added.

### **Updated Development and Commercialization Plan**

After thorough work under the leadership of our strengthened board, we were able to present an updated development and commercialization plan earlier this week. We will now focus more clearly on the use of Realheart TAH as a bridging treatment while waiting for organ transplantation - a sub-market where each percentage point of the patients currently on the waiting list for heart transplantation in Europe and the US corresponds to a potential sales revenue of 150 MSEK. At the same time, we have identified an opportunity to obtain reimbursement for Realheart TAH in the US already in the clinical trial phase, which would result in an earlier revenue flow than previously planned. In light of, among other things, delayed deliveries of components, we have updated the schedule for the remaining steps before the first clinical study and we now estimate that a trial application can be submitted at the turn of the year 2024/25.

## **Additional Puzzle Pieces in Place for the First Clinical Study**

We have now succeeded in establishing a preclinical test system that makes it possible to mimic the blood flow throughout the body and more comprehensively evaluate damage to red blood cells (hemolysis). Initial test results show that Realheart TAH induces 80% lower degree of hemolysis compared to today's market-dominant artificial heart. It is also gratifying that for the first clinical study in humans, we have a well-functioning collaboration in place with Professor Göran Dellgren, chief physician at the Transplantation Center and Thoracic Clinic at Sahlgrenska University Hospital.

## **International Attention for Realheart TAH**

In late August, we participated in ESAO in Italy and EUMS in Paris, two important European meetings that bring together experts in interventional cardiology. During the quarter, we were awarded Business Sweden's CATALYST grant of 250,000 SEK to map the addressable market for Realheart TAH in China.

Business Sweden also sponsored our presence at the Chinese International Import Expo (CIIE) in Shanghai where we participated on November 5-10. The visit followed closely on the heels of the China Heart Congress in early September, where the company was invited to present Realheart TAH to China's top cardiologists.

We have also attended scientific meetings and investor conferences in Finland, Malta, USA, China and Turkey and had the opportunity to demonstrate a prototype of the product's controller. In October, I was invited by the Heart Failure Policy Network to attend the launch of the Heart Failure Mission at the European Parliament in Brussels. Today, approximately 15 million individuals in Europe suffer from heart failure, a figure that is expected to increase by 90% by 2040. The Parliament's initiative aims to highlight the clinical need for new heart failure treatments and promote European investment in the field.

### **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 Najjar 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 September 30, 2023, the number of shares in Scandinavian Real Heart was 96 994 446.

## Largest Shareholder in the Company per 2023-09-30

	Country	Owner Type	Number of Shares	Votes (%)	Capital %
European Innovation Council Accelerator	Belgium	State, Municipality & region	18 300 000	18.9%	18.9%
Eskilstunahem Fastighets AB	Sweden	Other	7 900 018	8.1%	8.1%
Avanza Pension	Sweden	Individual	4 869 461	5.0%	5.0%
Azad Najjar	Sweden	Other	3 372 635	3.5%	3.5%
Nordnet Pensionsförsäkring	Sweden	Individual	1 666 109	1.7%	1.7%
Gilbert Raux	Sweden	Individual	1 115 700	1.2%	1.2%
Christer Jönsson	Sweden	Other	944 112	1.0%	1.0%
Big Bear Holding AB	Sweden	Other	907 500	0.9%	0.9%
Abbe Dikmen	Sweden	Individual	775 000	0.8%	0.8%
Jonas Rudberg	Sweden	Individual	727 140	0.7%	0.7%
Others			56 416 771	58.2%	58.2%
<b>Total</b>			<b>96 994 446</b>	<b>100.0%</b>	<b>100.0%</b>

## 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**

Year-end Report 2023 2024-02-15

Interim Report Q1 2024 2024-05-11

Annual Report 2023 2024-05-23

### **Annual General Meeting**

The company's annual general meeting is planned to be held Thursday, June 13th, 2024.

### **Submission of Interim Report**

Västerås, November 16, 2023

*The Board*

Scandinavian Real Heart AB

### **For Further Information, Please Contact**

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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: <http://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 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.*