

### **INTERIM REPORT**

2022-07-01 until 2022-09-30

Scandinavian Real Heart AB 556729-5588



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



# Significant Events During the Third Quarter of the Year

- July begins with a successful second implantation of the clinical version of Realheart TAH in sheep. The important milestone of 24-hour survival is achieved.
- At the end of August, one of Realheart's biomedical engineers presents the company's work on developing methods to measure blood damage in pulsatile pumps. This at a conference on blood damage caused by heart pumps, organised by the University of Rostock in Germany.
- September begins with the Realheart team attending the European Society of Artificial Organs (ESAO) conference in Austria. Three of the company's engineers present their research while the CEO and CTO are on hand to make contacts and represent the company.
- In the last days of September, the Company announces that the third implantation on animals is scheduled to take place in October.

## Significant Events After the End of the Period

- Three days into October, Realheart's CEO presents at FOKUS Patient, organised by Fokus Patient in collaboration with the Gift of Life and the European Society of Organ Transplantation, ESOT. The presentation is entitled "When organs are not enough" in the block on the future of organs and organ donation. Another speaker in the same session was Dr Bartley Griffith, an American surgeon who recently performed a high profile pig heart transplant in a human heart failure patient.
- Midway through October, Realheart is granted an additional loan from Almi of SEK 7.6 million, which will ensure continued rapid product development targeting clinical trials.



### Summary of Interim Report

### **Group Overview**

Third Quarter 2022 (2022-07-01 – 2022-09-30)

- Operating income amounted to 636 121 SEK.
- Earnings after financial items amounted to -11 073 084 SEK.
- Balance sheet total, 117 332 695 SEK.
- Earnings per share \* amounted to SEK -0.33.
- Equity / assets ratio was 86%.

### **Parent Company Overview**

First to Third Quarter 2022 (2022-01-01 – 2022-09-30)

- Operating income amounted to 636 121 (545 146) SEK.
- Earnings after financial items amounted to -10 985 243 (- 5 418 826) SEK.
- Balance sheet total, 116 441 628 (140 666 993) SEK.
- Earnings per share \* amounted to SEK -0.33 (-0.16) SEK.
- Equity / assets ratio was 86% (40%).

Third Quarter 2022 (2022-07-01 – 2022-09-30)

- Operating income amounted to 581 540 (16 445) SEK.
- Earnings after financial items amounted to
   -4 224 953(-1 410 135) SEK.
- Balance sheet total, 116 441 628 (140 666 993) SEK.
- Earnings per share \* amounted to SEK -0.13 (-0.04) SEK.
- Equity / assets ratio was 86% (40%).

Amounts in parentheses refer to the corresponding period last year.

<sup>\*</sup> Earnings per share: Earnings for the period divided by 33 183 461.

<sup>\*\*</sup> Equity ratio: Equity divided by total capital.



### Revenue and Result

Scandinavian Real Heart is 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 Q3 with 15.9 million. During the period, write-downs of capitalized costs for research and development were made by 0 million.

The item other external costs of 19.9 million consists of costs for purchased services of 8.9 million and various other costs of SEK 11.0 million. Of these costs, 15.9 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 22 million. Together with the grant of SEK 25.7 million that we have been granted from the EIC and which we will receive in 2022/2024, 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.



The development of Realheart® TAH continued with a high level of activity throughout the summer. We continued to work on our virtual implantations where we have now increased the number of patients to 15, and the pump has proven to be compatible with all male patients' bodies. The virtual implantations have also enabled us to start defining the dimensions for our follow-up product MiniHeart, which is intended for female patients among others. Nice synergies, in other words.

In July, we performed the second implantation on sheep and reached the milestone of 24 hours survival, which was extremely satisfying for the whole team. The pump did what it was supposed to do and the implantation proceeded smoothly, again providing a beneficial short time on the heart-lung machine before the complicated aftercare of the animal took place. Now that we are past the first critical day, we aim to gradually increase the survival time of each operation – and in parallel fine-tune the software of the controller based on the data we collect.

Something else I carry with me from this quarter is our participation in the ESAO conference in Austria. It brought together many of those who could be our future key customers and partners, and we had many fruitful discussions with representatives of the international clinical community, where we were able to learn about their experiences in treating patients with the artificial hearts available today. Several cardiac surgeons expressed an interest in our work, and several offered to help in various ways, such as with clinical trials.

"Implanting a TAH is the easiest thing you can do, you press a button and the patient is stable", said one doctor, and we found that the main obstacle to the use of artificial hearts is the risk of side effects and the need for continued care. There is no product that combines easy implantation with reduced blood damage and that gives the patient a high quality of life - but that is only a few years away now.

As we know, we have identified blood damage reduction as one of our key success factors, so it is particularly interesting to see how our competitors are working. During the conference, we were able to hear a presentation from a company that has chosen to have an external consultant perform their tests on blood from cows. We carry out our tests on human blood in our own laboratory – something few others have access to – and because human blood is three times more sensitive than that of cows, we expect to get more reliable answers on how the heart pump will perform in the human body.

In return, some of our engineers had the opportunity to present their work related to our testing activities to the conference participants. We have, as I often point out, a team with a unique collective expertise and I was really proud to see the great interest in Soteris Andreous, Joseph Bornoff and Faisal Zaman's methodology for durability, simulation and blood testing. We also received an award for our collaboration with the University of Bath.

The interest from students who want to collaborate with us is very high, and I see this as a channel for continued future recruitment of high-skilled talent. We currently have an MSc student from the University of Twente in the Netherlands who is working on making our blood testing rig more user-friendly. This will help tremendously as we perform tests every week and will continue to do so throughout the development process. Furthermore, our students from Uppsala University and the Royal Institute of Technology continue their work with us.

In August, our new CFO Jonas Caspari Bark joined us. Jonas will have a very important role as a unifying force at our headquarters in Västerås, as I am in the blood lab in Stockholm or abroad a lot of the time. We are building a good structure for the company so that I can focus on the right things as we continue our journey towards clinical trials and the market.

#### 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, almost 3,500 people die of heart failure in Sweden alone. Today, the best treatment is a heart transplant, but the number of donated hearts is only enough for 2% of those in need.

The idea behind Realheart was born in 1999, when the doctor and innovator Azad Najar made the first sketch of an artificial heart that fully mimics the biological one. 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 with the aim to reduce 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, blood pressure, oxygen saturation, pump function 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 good quality 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 permanent 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, 2022, the number of shares in Scandinavian Real Heart was 33,183,461.

### Largest Shareholder in the Company per 2022-09-30

Shareholders	Numbers of Shares	Votes (%)	Capital (%)
Najar Medical & Invention AB	3 262 635	9,83	9,83
Eskilstunahem Fastighets AB	1 650 006	4,97	4,97
Avanza Pension	1 473 437	4,44	4,44
Ålandsbanken ABP (finland)	852 181	2,57	2,57
Swedish, branch SEBP6			
Najar Bilend	516 263	1,56	1,56
Forslund Lars	489 474	1,48	1,48
Nordnet Pensionsförsäkring AB	470 720	1,42	1,42
Smartgroup Holding AB	417 316	1,26	1,26
Ewerth Staffan	350 000	1,05	1,05
SEB LIFESL 34064-01, SEB LIFE	304 449	0,92	0,92
Others	23 396 980	70,50	70,50
Total	33 183 461	100,00	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**

Year-end Report, 2022 2023-02-24 Interim Report Q1, 2023 2023-05-18

### **Submission of Interim Report**

Västerås, November 18, 2022 *The Board* Scandinavian Real Heart AB

### For Further Information, Please Contact

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### **Income Statement in Summary**

(SEK)

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GROUP			2022-07-01 2022-09-30	
			3 mån	
Operating Income				
Net turnover			10 000	
Other operating income			626 121	
			636 121	
Operating Expenses				
Other external expenses			-19 888 541	
Personnel costs			-6 973 449	
Capitalised expenses on own acount			15 889 095	
Depreciation and impairment of tangible a	nd intangible fixed asse	ets	-91 890	
Other operating expenses			-543 754	
			-11 608 539	
Operating Profil/Loss			-10 972 419	
Profit/loss from financial items				
Other interest income and similar items			0	
Interest expenses and similar items			-100 665	
			-100 665	
Profit/Loss After Financial Items			-11 073 084	
DADENT COMPANY	2022 07 24	2024 07 04	2022 04 64	20
PARENT COMPANY	2022-07-01	2021-07-01	2022-01-01	20

PARENT COMPANY	2022-07-01 2022-09-30 3 months	2021-07-01 2021-09-30 3 months	2022-01-01 2022-09-30 9 months	2021-01-01 2021-09-30 9 months
Operating income	10 000		10 000	
Other operating income	571 540 <b>581 540</b>	16 445 <b>16 445</b>	626 121 <b>636 121</b>	545 146 <b>545 146</b>
Operating expenses				
Other external expenses	-4 882 915	-3 363 869	-19 800 701	-16 333 774
Personnel costs	-2 293 602	-1 278 227	-6 973 449	-3 315 166
Capitalised expenses on own acount	2 824 415	3 336 349	15 889 095	14 058 159
Depreciation and impairment of tangible and				
intangible fixed assets	-23 679	-61 340	-91 890	-199 379
Other operating expenses	-396 258	-21 300	-543 754	-53 263
	-4 772 039	-1 388 387	-11 520 699	-5 843 423
Operating Profil/Loss	-4 190 499	-1 371 942	-10 884 578	-5 298 277
Profit/loss from financial investments				
Other interest income and similar items	0	0	0	0
Interest expenses and similar items	-34 454	-38 193	-100 665	-120 549
Profit/Loss After Financial Items Profit/Loss Before Tax Result of the Period	-4 224 953 -4 224 953 -4 224 953	-1 410 135 -1 410 135 -1 410 135	-10 985 243 -10 985 243 -10 985 243	-5 418 826 -5 418 826 -5 418 826

### Balance Sheet in Summary (SEK)

GROUP	2022-09-30
ASSETS	
Fixed Assets	
Intangible fixed assets	
Capitalised expenditure on development and similar work	92 135 078
Concessions, patents, licences, trademarks and similar rights	
Tangible fixed assets	
Equipment, tools, fixtures and fittings	55 210
Total Fixed Assets	92 190 288
Current Assets	
Advances to Suppliers	1 301 400
Current receivables	
Accounts receivable	12 500
Tax receivables	0
Other receivables	1 308 661
Prepaid expenses and accrued income	442 289
	1 763 450
Cash and bank balances	22 077 557
Total Current Assets	25 142 407
TOTAL ASSETS	117 332 695
EQUITY AND LIABILITIES	
Equity Capital	
Share capital	3 318 346
ongoing unregistered share issue	0
Fund for development expenditure, patents, licences, trademarks	92 135 078
Other equity incl. profit for the year	-5 134 406
Total Equity	100 587 830
Non-Current Liabilities	
Liabilities to credit institutions	1 708 074
Current Liabilities	
Liabilities to credit institutions	621 118
Advances from grants	9 401 184
Accounts payable	2 897 030
Tax liabilities	74 783
Other current liabilities	332 768
Accrued expenses and deferred income	1 709 907
Total Short-term Liabilities	15 036 791
TOTAL EQUITY AND LIABILITIES	117 332 695

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PARENT COMPANY	2022-09-30	2021-09-30	2021-12-31
ASSETS Fixed Assets			
Intangible Fixed Assets			
Capitalised expenditure on development and similar work Concessions, patents, licences, trademarks and similar rights	85 710 298	63 713 066 4 730 860	68 409 775 4 993 788
Tangible Fixed Assets			
Equipment, tools, fixtures and fittings  Financial Fixed Assets	55 210	124 681	90 949
Shares in group companies	78		
Total Fixed Assets	85 765 586	68 568 607	73 494 512
Current Assets			
Current receivables	42.500	0	0
Accounts receivable	12 500	0	0
Receivables from group companies Other receivables	7 458 948 699 296	0 2 855 258	0 1 337 270
Prepaid expenses and accrued income	427 828	9 127 100	310 774
Cash and bank balances	22 077 470	60 116 028	42 672 700
Total Current Assets	30 676 042	72 098 386	44 320 744
TOTAL ASSETS	116 441 628	140 666 993	117 815 256
EQUITY AND LIABILITIES			
Equity Share capital	3 318 346	2 255 846	3 318 346
Ongoing share issue	0	1 062 500	0-20166
Fund for development expenditures	85 710 298	71 896 707	68 409 773
Balanced result	22 606 402	52 708 658	50 045 593
Profit for the period	-10 985 243	-5 418 826	-10 483 500
	11 621 159	47 289 832	39 562 093
Total Equity	100 649 803	122 504 885	111 290 212
Non-Current Liabilities			
Other liabilities	1 708 074	2 329 193	2 173 913
Current Liabilities			
Liabilities to credit institutions	621 118	621 118	621 118
Advances from grants	9 401 184	0	0
Accounts payable	1 943 992	11 898 506	2 209 264
Tax liabilities	74 783	12 075	17 867
Other current liabilities	332 768	2 008 625	230 628
Accrued expenses and deferred income  Total Short-term Liabilities	1 709 906 <b>14 083 751</b>	1 292 591	1 272 254
TOTAL EQUITY AND LIABILITIES	116 441 628	15 832 915 140 666 993	4 351 131 117 815 256

### Cash Flow Statement in Summary

(SEK)

GROUP	2022-01-01 2022-09-30 9 months
Cash Flow From Operations	
Cash flow from operating activities	-11 073 084
Adjustments for non-cash items	117 757
Income Tax Paid	0
Cash Flow From Operations Before	
Changes in Working Capital	-10 955 327
Change in accounts receivable	-12 500
Change in current receivables	-102 907
Change in supplier advance	-1 301 400
Change in advances of public subsidies	9 401 184
Change in accounts payable	687 766
Change in current liabilities	596 709
Cash Flow From Operating Activities	-1 686 475
Investing Activities	
Investments in intangible assets	-18 787 665
Cash Flow From Investing Activities	-18 787 665
Financing Activities	
Warrants	344 834
Change loans	-465 838
Cash Flow From Financing Activities	-121 004
Cash Flow For the Period	-20 595 143
Cash and Cash Equivalents at the Start of the Period	42 672 700
Cash and Cash Equivalents at the End of the Period	22 077 557

### Cash Flow Statement in Summary

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PARENT COMPANY	2022-07-01 2022-09-30 3 months	2021-07-01 2021-09-30 3 months	2022-01-01 2022-09-30 9 months	2021-01-01 2021-09-30 9 months
Cash Flow From Operations				
Cash flow from operating activities	-4 224 953	-1 410 134	-10 985 243	-5 418 826
Adjustments for non-cash items	23 679	61 340	91 890	199 379
Cash Flow From Current Operations Before				
Changes in Working Capital	-4 201 274	-1 348 794	-10 893 353	-5 219 447
changes in working capital	4201274	1 540 754	10 055 555	3213447
Changes in accounts receivable	-12 500	0	-12 500	0
Changes in current receivables	-7 063 842	-3 825 260	-6 938 028	-10 533 339
Changes in advances from grants	10 604 752		9 401 184	
Changes in accounts payable	-1 075 218	10 119 119	-265 272	10 410 370
Changes in current liabilities	109 220	-5 525 986	596 707	1 867 330
Cash Flow From Operating Activities	-1 638 862	767 873	-8 111 262	-3 475 006
Investing Activities				
Investments in intangible assets	-631 916	-3 680 319	-12 362 886	-14 627 202
Investments in financial assets	-78	0	-78	0
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Cash Flow From Investing Activities	-631 994	-3 680 319	-12 362 964	-14 627 202
Financing Activities				
New share issue	0	56 229 154	0	56 229 154
Warrants	344 834	0	344 834	0
Change loans	-155 280	-155 279	-465 838	-465 838
Code Electric Code Code Code Code	400.557	50.072.075	434.007	FF 752 246
Cash Flow From Financing Activities	189 554	50 073 875	-121 004	55 763 316
Cash Flow For the Period	-2 081 302	51 812 635	-20 595 230	37 661 028
Cash and Cash Equivalents at the Start of the Period	24 158 772	8 303 393	42 672 700	22 455 000
Cash and Cash Equivalents at the End of the Period	22 077 470	60 116 028	22 077 470	60 116 028

# REALHEART

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