



Q4

YEAR-END REPORT

2022-01-01 until 2022-12-31

Scandinavian Real Heart AB
556729-5588

REALHEART

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



Summary of the Year-end Report

Group Overview (SEK)	2022-10-01	2021-10-01	2022-01-01	2021-01-01
	2022-12-31	2021-12-31	2022-12-31	2021-12-31
	3 mon	3 mon	12 mon	12 mon
Operating income	31 468		667 589	
Earnings after financial items	-2 914 829		-13 987 911	
Balance Sheet total	119 816 255		119 816 255	
Equity / Assets ratio	81%		81%	
Earnings per share	-0.09		-0.42	
Number of shares	33 183 461		33 183 461	
Parent Company Overview (SEK)	2022-10-01	2021-10-01	2022-01-01	2021-01-01
	2022-12-31	2021-12-31	2022-12-31	2021-12-31
	3 mon	3 mon	12 mon	12 mon
Operating income	31 468	-3 288	667 589	541 858
Earnings after financial items	-2 824 786	-5 064 674	-13 810 029	-10 483 500
Balance Sheet total	111 229 225	117 815 256	111 229 225	117 815 256
Equity / Assets ratio	88%	94%	88%	94%
Earnings per share*	-0.09	-0.15	-0.42	-0.32
Number of shares**	33 183 461	33 183 461	33 183 461	33 183 461

Proposed Treatment of the Company's Earnings

The Board of Directors propose that the company's earnings be carried forward in the amount of 12 280 481.

Share premium reserve	164 712 421
Retained earnings	-138 621 911
Result for the year	- 13 810 029
Total	12 280 481

No dividends will be paid to shareholders

* Equity ratio: equity divided by total capital.

Amounts in brackets refer to the corresponding period of the previous year.

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



Revenue and Results

Scandinavian Real Heart 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 the year with 21.2 MSEK. During the period, write-downs of capitalized costs for research and development were made by 0 MSEK.

The item other external costs of 24.5 MSEK consists of costs for purchased services of 10.2 MSEK and various other costs of 14.3 MSEK. Of these costs, 21.2 MSEK has been capitalized.

Financial Position

With a cash balance of 11.3 MSEK, the company has funding that will last into second quarter of 2023. In order to solve the Company's longer-term financing needs, Realheart works continuously to evaluate alternatives for further capitalization.



Significant Events During the Fourth Quarter of the Year

- **In early October**, Realheart's CEO Ina Laura Perkins will appear at the Transplantation Forum organised by Focus Patient in collaboration with The Gift of Life and the European Society of Organ Transplantation, ESOT, at the City Conference Center in Stockholm. Among the speakers will be Dr Bartley Griffith, an American surgeon who recently performed a high-profile pig heart transplant for a human.
- **At the end of October**, it is announced that Realheart's artificial heart is featured in a German TV documentary on heart disease and new scientific developments, broadcast on ZDF on 25 October. Both Realheart's founder Azad Najar and Dr Dilek Gürsoy, who is part of the company's surgical team for the ongoing animal studies, are interviewed in the programme.
- **The last thing to happen in October** is that the third implantation on animals is completed and trials continue. Once again, the implantation went quickly and progress was made, among other things, in the optimal placement of the pump.

Significant Events After the End of the Period

- **A step into January**, the company reaches a new milestone with Realheart TAH. Since the series of animal trials with the clinical version of the company's artificial heart began in 2022, Realheart has been able to progressively increase survival time from the previous milestone of one day to four days. After implantation, the animal has been able to stand up and eat. In addition, several key performance criteria were confirmed.
- **In the second half of January**, a press release announces that Realheart and KTH are optimising heart function in Sweden's first patient simulator. The collaboration between Realheart and KTH to develop the simulator (scientific term: "hybrid simulator") started in 2022 after a grant of SEK 4 million from Vinnova Smart Elektronik*.
- **At the end of January**, it is announced that Dr. Ulf Kjellman strengthens Realheart's medical council. Ulf Kjellman has over 35 years of experience in cardiac and thoracic surgery and was involved in the introduction of HeartMate II, HeartMate 3, Centrimag, Maquet pumps, Berlin Excor and SynCardia TAH, among others.
- **The last event of January** is that the company is offering subscription right holders the right to subscribe to HEART TO1. The subscription period will run from 1-28 February 2023.

**Strategic Innovation Programme Smarter Electronic Systems - a joint effort by Vinnova, Formas and the Swedish Energy Agency.*



CEO Ina Laura Perkins

"Our heart surgeons speak warmly about our artificial heart"

In the last three months of the year, we made progress in three areas: international marketing, soft funding and our animal studies. In October, our Realheart® TAH was featured in prime time on the German TV channel ZDF in a documentary on heart disease.

A German TV crew visited one of our surgeries to interview the company's founder Azad Najar and the heart surgeon Dilek Gürsoy who performs the operations. Interviewer was a German celebrity chef who has a heart condition himself, and the show followed a young woman with heart failure on her road to a successful heart transplant. The documentary highlights Realheart as a promising alternative solution to the organ shortage.

Germany is one of the largest markets in Europe for artificial hearts. To learn more, I visited the clinic that performs the most heart pump surgeries in the country: the Medical University of Hannover. There I interviewed heart surgeon Professor Jan Schmitto, who said that in Germany alone, 40,000–60,000 artificial hearts are needed each year. This means that we have underestimated the need.

Proof of the strong need is the sales forecast for 2023 from our European competitor. They started selling in November and expect to sell over 100 hearts in the first year at revenues of €10–13 million and scale up production to 1000 hearts by 2027. This is great news for heart failure patients in Europe, but it is only enough for a fraction of patients. Doctors are reminding us that even more artificial hearts are urgently needed.

The situation is similar in the rest of the world. In December, I spoke at the Critical Heart Disease Congress in China. The digital conference has so far been viewed by 24,000 viewers, including doctors and healthcare professionals from Australia, the UK, Austria, Italy, the US and China. I also gave an introduction to the International Society for Mechanical Circulatory Support (ISMCS), for which I have been on the Board since May. Through these networks, we can find the right partners and future customers faster, and raise awareness of artificial hearts as a cure for heart failure. The marketing has already had an impact as I have received

enquiries from doctors in Brazil and elsewhere.

To start clinical trials, we need good results from animal studies in addition to blood and durability tests. During the year, we have worked on the surgical process and animal care, for example on the settings of the heart-lung machine. We have realized that this is not readily available knowledge but that we are building up valuable unique know-how within the team. Therefore, we decided not to communicate as frequently and in as much detail about our animal studies as we had done in the past. I understand that this may frustrate shareholders, but I can assure you that we have quietly made great progress: 4 days of survival without blood damage.

Developing an artificial heart requires excellence throughout the entire chain - from idea to marketing and sales. This chain is complete with us, we have all the pieces needed to get to market. Here, our international expertise from several artificial heart projects contributes greatly, as it is a challenge to find equivalent in Sweden. I am convinced that our diversity contributes strongly to our success. It is awesome that we have over 100 years of combined expertise.

In addition to a strong team and good results, continued funding is needed to reach the market. Therefore, we are working on the due diligence process for the European Innovation Council fund which has nominated us for €15 million investment, as well as on finding soft funding. We are very grateful that ALMI chose to continue supporting our work with an innovation loan of 7.6 million SEK. In the first quarter of 2023, our shareholders can further strengthen our cash position via the share option. The funding will be used for animal studies and to start the blood tests on the clinical version of Realheart TAH - we are proceeding nicely according to our plan in other words.

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 2022-12-31

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	1 478 568	4.46	4.46
Ålandsbanken ABP (Finland) Svensk filial SEBP6	801 710	2.42	2.42
Najar, Bilend	516 263	1.56	1.56
Forslund, Lars	489 474	1.48	1.48
Nordnet Pansionsförsäkring AB	468 216	1.41	1.41
Smartgroup Holding AB	417 316	1.26	1.26
Ewerth, Staffan	350 000	1.05	1.05
Raux, Gilbert	314 756	0.95	0.95
Others	23 434 517	70.61	70.61
Totalt	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.

2022 is the first year of group reporting, therefore there is no comparison column for the group for the previous year.

Audit Review

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

Upcoming Financial Reports

Annual Report	2023-04-20
Interim Report Q1, 2023	2023-05-11
Annual General Meeting	2023-05-26
Interim Report Q2, 2023	2023-08-24
Interim Report Q3, 2023	2023-11-16
Year-end Report 2023	2024-02-15

Submission of Interim Report

Västerås, Februari 24, 2023
The Board
Scandinavian Real Heart AB

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Income Statement in Summary

(SEK)

GROUP	2022-10-01	2022-01-01
	2022-12-31	2022-12-31
	3 mån	12 mån
Operating Income		
Net turnover	0	10 000
Other operating income	31 468	657 589
	31 468	657 589
Operating expenses		
Other external expenses	-4 628 295	-24 516 836
Personnel cost	-3 067 712	-10 041 161
Capitalized expenses on own account	5 272 788	21 161 883
Depreciation and impairment of tangible and intangible fixes assets	-23 476	-115 366
Other operating expenses	-462 989	-1 006 742
	-2 909 684	-14 518 222
Operating Profit / Loss	-2 878 216	-13 850 633
Other interest income and similar items	423	423
Interest expenses and similar items	-37 036	-137 701
	-36 613	-137 278
Profit / Loss After Financial Items	-2 914 829	-13 987 911

Balance Sheet in Summary

(SEK)

GROUP	2022-12-31
ASSETS	
<i>Fixed Assets</i>	
<i>Intangible fixes assets</i>	
Capitalized expenditure on development, patents licences and trademarks	105 051 108
<i>Tangible fixed assets</i>	
Equipment, tools, fixtures and fittings	46 068
Total Fixed Assets	105 097 176
<i>Current Assets</i>	
Advances to Suppliers	1 276 056
<i>Current receivables</i>	
Accounts receivables	0
Tax receivables	0
Other receivables	1 936 905
Prepaid expenses and accrued income	247 080
	2 183 985
Cash and bank balances	11 259 038
Total Current Assets	14 719 079
TOTAL ASSETS	119 816 255
SHAREHOLDERS' EQUITY AND LIABILITIES	
<i>Shareholders' Equity</i>	
Share capital	3 318 346
Ongoing unregistered share issue	0
Other contributed capital	164 712 421
Other equity incl. profit for the year	-70 385 545
Total Equity	97 645 222
<i>Non-Current Liabilities</i>	
Liabilities to credit institutions	1 552 795
<i>Current Liabilities</i>	
Liabilites to credit institutions	621 118
Advances from Grants	7 960 800
Accounts payable	10 331 385
Tax liabilities	118 582
Other current liabilities	397 679
Accrued expenses and deferred income	1 188 674
	20 618 238
 TOTAL SHAREHOLDER'S EQUITY AND LIABILITIES	 119 816 255

Cash Flow Statement in Summary

(SEK)

GROUP	2022-10-01	2022-01-01
	2022-12-31	2022-12-31
	3 mån	12 mån
Cash Flow from Operations		
Cash flow from operating activities	-2 914 829	-13 987 911
Adjustment for non-cash items	-4 303	113 453
Cash Flow from Operations before changes in Working Capital	-2 919 132	-13 874 458
Change in Account Receivables	12 500	0
Change in Current Receivables	-433 034	-535 941
Change in Supplier Advances	25 344	-1 276 056
Change in Accounts Payable	7 434 355	8 122 121
Change in Current Liabilities	-412 524	184 185
Cash Flow from Operating Activities	3 707 509	-7 380 149
Investing Activities		
Investments in intangible assets	-14 370 748	-23 757 229
Cash Flow from Investing Activities	-14 370 748	-23 757 229
Financing Activities		
Warrants	0	344 834
Change in Loans	-155 280	-621 118
Cash Flow from Financing Activities	-155 280	-276 284
Cash Flow for the Period	-10 818 519	-31 413 662
Cash and Cash Equivalents at the beginning of the period	22 077 557	42 672 700
Cash and Cash Equivalents at the end of the period	11 259 038	11 259 038

Income Statement in Summary

(SEK)

PARENT COMPANY	2022-10-01	2021-10-01	2022-01-01	2021-01-01
	2022-12-31	2021-12-31	2022-12-31	2021-12-31
	3 mån	3 mån	12 mån	12 mån
Income				
Operating Income	0	0	10 000	0
Other Operating Income	31 468	-3 288	657 589	541 858
	31 468	-3 288	667 589	541 858
Operating Expenses				
Other external expenses	-4 538 253	-7 337 435	-24 338 954	-23 671 209
Personnel cost	-3 067 712	-2 306 375	-10 041 161	-5 621 541
Capitalized expenses on own account	5 272 788	4 696 709	21 161 883	18 754 868
Depreciation and impairment of tangible and intangible fixes assets	-23 476	-34 307	-115 366	-233 686
Other operating expenses	-462 988	-44 002	-1 006 742	-97 265
	-2 819 641	-5 025 410	-14 340 340	-10 868 833
Operating Profit/Loss	-2 788 173	-5 028 698	-13 672 751	-10 326 975
Interest income and similar items	423	0	423	0
Interest expenses and similar items	-37 036	-35 976	-137 701	-156 525
	-36 613	-35 976	-137 278	-156 525
Profit/loss after financial items	-2 824 786	-5 064 674	-13 810 029	-10 483 500
Profit/loss before taxes	-2 824 786	-5 064 674	-13 810 029	-10 483 500
Net Income for the period	-2 824 786	-5 064 674	-13 810 029	-10 483 500

Balance Sheet in Summary

(SEK)

PARENT COMPANY	2022-12-31	2021-12-31
ASSETS		
Fixed Assets		
<i>Intangible Fixed Assets</i>		
Capitalized expenditure on development, patents, licences and trademarks	88 633 000	73 403 563
<i>Tangible Fixes Assets</i>		
Equipment, tools, fixtures and fittings	46 068	90 949
<i>Financial Fixes Assets</i>		
Shares in group companies	11 320 840	0
Total Fixes Assets	99 999 908	73 494 512
<i>Current Assets</i>		
Accounts receivable	0	0
Receivables from group companies	0	0
Other receivables	747 123	1 337 270
Prepaid expenses and accrued income	232 901	310 774
	980 024	1 648 044
Cash and cash equivalents	10 249 293	42 672 700
Total Current Assets	11 229 317	44 320 744
TOTAL ASSETS	111 229 225	117 815 256
SHAREHOLDERS' EQUITY AND LIABILITIES		
<i>Shareholders' Equity</i>		
Share Capital	3 318 346	3 318 346
Fund for development expenditures, patents, licences and trademarks	82 226 190	68 409 773
	85 544 536	71 728 119
Share premium reserve	164 712 421	164 712 421
Retained Earnings	-138 621 911	-114 666 829
Profit/loss for the year	-13 810 029	-10 483 500
	12 280 481	39 562 092
Total Shareholders' Equity	97 825 017	111 290 211
<i>Non-Current Liabilities</i>		
Other liabilities	1 552 795	2 173 913
<i>Current Liabilities</i>		
Liabilities to credit institutions	621 118	621 118
Advances from Grants	7 960 800	0
Accounts payable	1 564 560	2 209 264
Tax liabilities	118 582	17 867
Other current liabilities	397 679	230 628
Accrued expenses and deferred income	1 188 674	1 272 254
	11 851 413	4 351 131
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES	111 229 225	117 815 256

Cash Flow Statement in Summary

(SEK)

PARENT COMPANY

	2022-10-01 2022-12-31 3 mån	2021-10-01 2021-12-31 3 mån	2022-01-01 2022-12-31 12 mån	2021-01-01 2021-12-31 12 mån
Cash Flow from Operations				
Cash flow from operating activities	-2 824 786	-5 064 674	-13 810 029	-10 483 500
Adjustment for non-cash items	23 476	34 307	115 366	233 686
Cash Flow from Operations before changes in Working Capital	-2 801 310	-5 030 367	-13 694 663	-10 249 814
Changes in Working Capital				
Change in Accounts Receivable	12 500	0	0	0
Change in Current Receivables	7 606 047	10 334 315	668 019	-199 025
Change in Accounts Payables	-379 432	-9 689 242	-644 704	721 128
Changes in Current Liabilities	-412 521	-1 792 542	184 186	74 788
Cash Flow from Operating Activities	4 025 284	-6 177 836	-13 487 162	-9 652 923
Investing Activities				
Investments in Intangible Assets	-4 377 419	-4 960 212	-7 339 121	-19 587 414
Investments in Financial Assets	-11 320 762	0	-11 320 840	0
Cash Flow from Investing Activities	-15 698 181	-4 960 212	-18 659 961	-19 587 414
Financing Activities				
New Share issue	0	-6 149 999	0	63 480 012
Share issue expenses	0	0	0	-13 400 857
Warrants	0	0	344 834	0
Change in Loans	-155 280	-155 279	-621 118	-621 118
Cash Flow from Financing Activities	-155 280	-6 305 278	-276 284	49 458 037
Cash Flow for the Period	-11 828 177	-17 443 327	-32 423 407	20 217 700
Cash and Cash equivalents at the beginning of the period	22 077 470	60 116 028	42 672 700	22 455 000
Cash and Cash equivalents at the end of the period	10 249 293	42 672 700	10 249 293	42 672 700

REALHEART

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