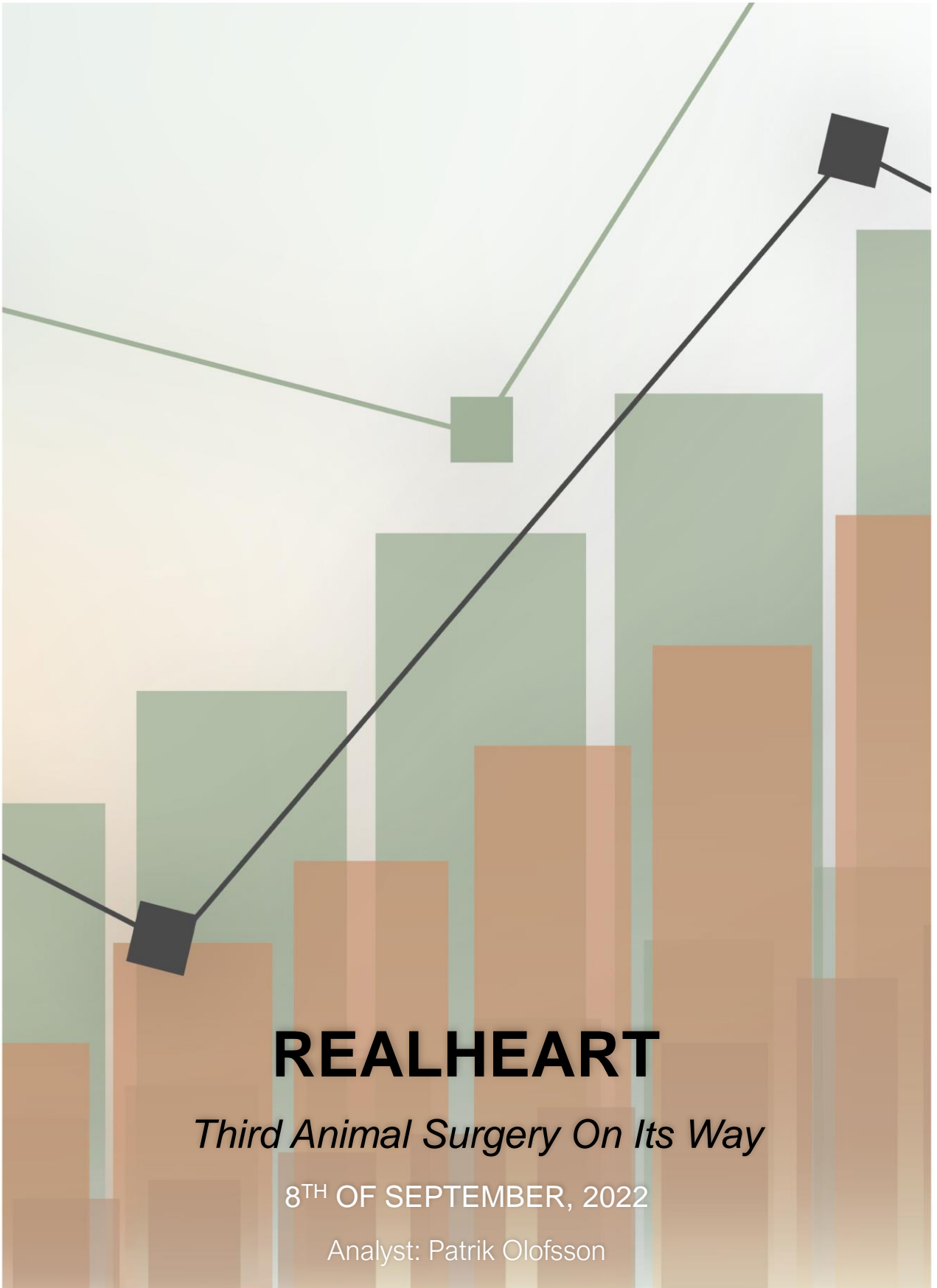


# EQUITY RESEARCH REPORT



# REAL HEART (HEART)

## THIRD ANIMAL SURGERY ON ITS WAY



Scandinavian Realheart AB (publ) ("Realheart" or the "Company") holds the world's first unique and patented four chamber Total Artificial Heart ("TAH"), which mimics the human heart's blood flow. With a cash position that still remains strong, the Company is closing in on its third live animal study. Expectations of human trials are still set for 2024, where we maintain our estimate of market launch during the latter part of 2025. From this point, sales could increase rapidly, with revenues reaching SEK276 M in 2028 in our Base scenario. Based on an applied P/S multiple of 5x (5), and an applied discount rate of 18%, this yields a present value per share of SEK 9.4. Before market launch, we continue to see several key value-driving activities, where steps in right direction could reduce the current valuation discount.

### ▪ Second Animal Surgery Has Been Conducted...

The clinical version of the Realheart® TAH – the version that will eventually be used in humans – has during July been successfully implemented in a second animal trial, following the first successful implantation of the Company's TAH reported during early June. Overall, the surgery was rapid and went well and marks a key milestone where time of survival reached over 24 hours.

### ▪ ... And A Third Is One Its Way

On the second day following the implant in the sheep, the animal moved a lot which resulted in dislocating some of the life support equipment and the decision was taken to end the study. Measures have been taken to avoid recurrence. The Company plans to achieve longer survival times in future sheep studies, where the next surgery is planned for September 2022. Hence, this will be very important to monitor from an investor perspective.

### ▪ Listed Peer Illustrate the Valuation Potential

Realheart TAH has a unique design that mimics the biological heart. The design, like the biological heart, enables Realheart TAH to deliver a pulsatile blood flow gentle to the blood, in an extremely energy effective way. So far, there is nothing that suggest that Realheart TAH will not be significantly better than what is on the market today. Realheart's market cap is approx. EUR11 M which can be compared to Carmat SA, the developer of the bioprosthetic artificial heart Aeson®, that have a market cap of approx. EUR258 M, hence a 24x greater than Realheart.

### ▪ Valuation Range Unchanged

As Realheart develops in line with our expectations, we choose in conjunction with the Q2 report to make only minor adjustments to our forecasts and maintain our valuation range for Base- Bull-, and Bear. Hence, we still see an attractive risk reward from current trading levels.

### SHARE PRICE | SEK 3.4

#### VALUATION RANGE, PRESENT VALUE 2028Y FORECAST

<b>BEAR</b> SEK 2.5	<b>BASE</b> SEK 9.4	<b>BULL</b> SEK 12.6
------------------------	------------------------	-------------------------

*The valuation is derived as a present value of sales forecasted in the year 2028. The potential valuation increase is expected to be gradual, given that assumed events occur.*

#### SCANDINAVIAN REALHEART AB

Share Price (2022-09-07) (SEK)	3.4
Number of Shares Outstanding	33,183,411
Market Cap (MSEK)	112.8
Net Cash (-)/Debt(+) (MSEK)	-39.4 <sup>1</sup>
Enterprise Value (MSEK)	79.4
W.52 Price Interval (SEK)	2.81 – 6.98
Stock Exchange	Nasdaq First North Growth Market

#### SHARE PRICE DEVELOPMENT

1 Month	-2.8 %
3 Months	-17.7 %
1 Year	-41.9 %
YTD	-34.9 %

#### TOP SHAREHOLDERS (AS OF 2022-06-30)

Najar Medical & Invention AB	9.8 %
Eskilstunahem Fastigheter AB	5.0 %
Försäkrings AB Avanza	4.4 %
Ålandsbanken ABP (Finland) Svensk filial	2.6 %
Najar Bilend	1.6 %

#### CEO AND CHAIRMAN OF THE BOARD

CEO	Ina Laura Perkins
Chairman of the Board	Christer Norström

#### FINANCIAL CALENDER

Quarterly Report #3 2022	2022-11-18
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FORECAST (BASE), SEK M	2025E	2026E	2027E	2028E	2029E	2030E
Revenues	12	42	108	276	480	780
<b>Gross Profit</b>	<b>5</b>	<b>19</b>	<b>53</b>	<b>141</b>	<b>254</b>	<b>429</b>
Gross margin	40%	45%	49%	51%	53%	55%
Total operating costs	-41	-46	-60	-91	-132	-156
<b>EBIT</b>	<b>-36</b>	<b>-27</b>	<b>-7</b>	<b>50</b>	<b>122</b>	<b>273</b>
EBIT margin	neg.	neg.	neg.	18%	25%	35%
P/S	9,4	2,7	1,0	0,4	0,2	0,1
EV/S	6,1	1,7	0,7	0,3	0,2	0,1
EV/EBIT	neg.	neg.	neg.	1,5	0,6	0,3

<sup>1</sup>Including a reported cash position of SEK24.2 M during end of June 2022, as well as upcoming grants from EIC of SEK25.7 M during 2022/2023. Also include assumed burn rate July – August 2022.

# INVESTMENT THESIS

## Addressing A Rapid Growing Blue Ocean Market

Each year, only 8,000 heart failure patients globally are saved through heart transplants, which corresponds to only ~3% of patients in need. In the US, more than 300,000 people die of heart failure each year, and forecasts show that heart failure diagnoses will increase to about 8 million by 2030. Treatments for heart failure can be done either through medication, or heart transplantation. The waiting times are often long and the current "transplantation rate" is forecasted to cover less than 10% of the actual need, as the mortality rate of advanced heart failure is up to 90% within a year. An alternative for replacing the failing heart is to provide a so-called Total Artificial Heart (TAH), which is done by surgery in the same way as in a heart transplantation. Besides from Carmat who have reached the market with their bioprosthetic artificial heart, Aeson®, there is today only one other commercialised TAH available on the market, namely SynCardia (US). SynCardia Systems LLC's sales amounted to approx. USD16 M year 2019 and are forecasted to increase to approx. USD65 M in 2029, which is equivalent to a Compounded Annual Growth Rate (CAGR) of ~15%. For Realheart, this is interesting in several aspects; firstly, it means that an established market player has "paved the way", which favours Realheart's growth journey, secondly, that the number of market players are still so small that the TAH market can almost be compared with a *Blue Ocean*. Given a successful product and clinical development, Realheart is estimated to obtain market approval in 2025.

**~15 %  
ANNUAL  
MARKET  
GROWTH  
2019-2029E**

## Value Drivers Within The Next 12-36 Months

Realheart's lab test results on blood look very promising and short term pre-clinical animal trials have been successful. Long term trials have been initiated during 2021 and so far, there is nothing to suggest that Realheart TAH will not be significantly better than what is on the market today. To initiate clinical trials, three main types of data must be submitted to the FDA for review: animal trial data from a certified laboratory conducted according to Good Laboratory Practice (GLP) for six animals supported for 60 days, whereas in Europe Carmat has conducted implants on only four animals supported up to 10 days to gain approval to initiate clinical trials, reliability study data conducted on a set of eight pumps under the worst pumping conditions for six months, and blood test (hemolysis) data of the product in comparison with a device in clinical use. From this point, the first in-human study, consisting of end-stage heart failure patients in immediate need of life-saving treatment, is to be initiated. In parallel, Realheart continues the work with identifying suitable partners with the right experience and knowledge for high-quality medtech products. All of these events compose important steps until market launch, and also constitutes as value drivers within the next 12-36 months, which can result in an increase in the share price. An interesting comparison can be made with the French company Carmat, which has some technical differences compared to Realheart's TAH, but with a similar purpose. Carmat have a Market Cap of approx. EUR258 M, which can be compared to Realheart's EUR11 M, i.e., a ~24x greater valuation. From an investor perspective, it can be argued, based on Carmat's present valuation, that the valuation of Realheart may increase gradually as the Company gets closer to market launch.

## Forecast And Valuation: A Summary

In a Base scenario, Realheart is estimated to reach sales of approx. SEK276 M during 2027, and from that point grow at an average rate of 68% per year until 2030, reaching sales of approx. SEK780 M, corresponding to 0.5% of the addressable market. Steps still remain before the potential market launch, which is a risk that must be considered in the financial scenarios that are presented in this analysis. With a target multiple of P/S 5x on estimated sales during the year 2028, and a conservative discount rate of 18%, which accounts for the time specific risk of events that are far away and have not yet occurred, this yields, in a Base scenario, a fundamental net present value per share of SEK 9.4.

**SEK ~780 M  
REVENUES  
2030E**

## Strengthen Cash Position But A Long Road To Walk Until Market Launch

The rights issue in September 2021 brought in approx. SEK61.5 M. At the end of June 2022, cash amounted to SEK24.2 M and, on top of this, Realheart has an incoming grant of approx. SEK25.7 M from EIC during 2022/2023. With this in mind, and an assumed burn rate of approx. SEK-4.0 M / month, Realheart has secured finance for the business for a 9-month period going forward (Q2 2023). For beyond that point, Realheart will need to obtain further external capital in order to finance various investments before a market launch is possible, where we assume that fundings could be obtained via a combination of additional shareholder capital and so-called "soft money", e.g., via grants and other R&D re-imbursment schemes.

# FINANCIAL FORECAST

## Revenue Forecast 2025-2030

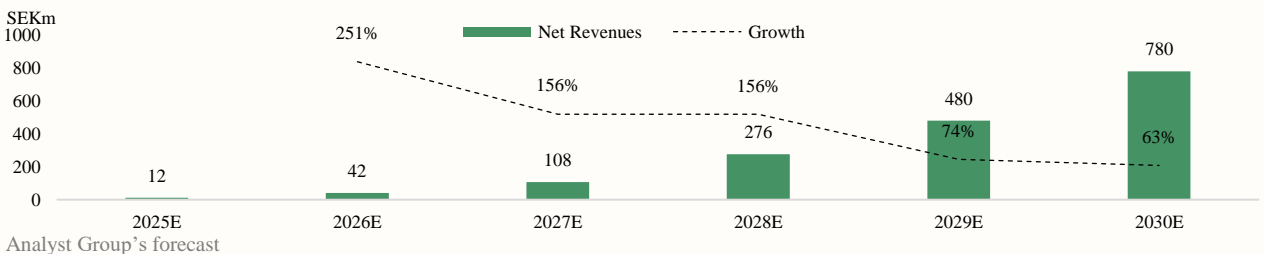
Analyst Group’s financial estimates of Realheart’s revenues are based on 2025 being the year for the market launch of the TAH for normal-sized individuals, where the forecast period extends to 2030. Realheart’s *Go-To-Market* strategy is to provide the product directly through an in-house sales organization by regional salesmen, alternatively via partners and / or distributors, primarily to hospitals within Europe and the US. In other geographic regions, the product may be sold primarily through partners and distributors. Business contracts are assumed to be initiated by for example a cardiologist or a cardiothoracic surgeon, where the hospitals then pay for the purchase of Realheart’s TAH and receives compensation from the government or insurance companies, depending on the geographical market. The patient group that Realheart TAH primarily addresses are individuals that suffer from either chronic heart failure, and/or acute heart failure, a group consisting of millions of people within Europe and the US. However, not all patients within these diagnostic groups are suitable for a TAH treatment, e.g. the patient should not be too old due to the extent of the surgery, and the patient’s chest needs to be large enough for the mechanical heart to fit. The potential market for Europe and the US is estimated to consist of a total of approx. 129,000 patient/year, equivalent to approx. USD16 billion in annual sales. Per patient, this corresponds to a product price of about SEK1.2 M, which is in line with the price for the SynCardia TAH. However, Carmat’s early sales suggest a price in a range twice as high, indicating that Realheart’s price estimate is conservative. Over the past 35 years, SynCardia TAH has been implanted in over 2,000 patients, corresponding to an average of 60 patients/year and thus only ~0.05% of the annual market size of 129,000 patients. The low market penetration is the result of low user-friendliness and +35-year-old technology which causes several side effects.

**EVEN AT A SMALLER MARKET SHARE, SALES CAN INCREASE RAPIDLY**

Given that Realheart can initiate a market launch during 2025, there should be room for the Company to take a large market share. With a conservative assumption that Realheart gradually increases their market share to 0.5% of the target group by 2030, this would translate to about 650 patients and total sales of SEK780 M. The level of revenues may be perceived as sensational or even striking, but it can be compared with SynCardia TAH’s sales, which in 2019 amounted to approx. SEK140 M, and are expected to rise to SEK~565 M year 2029.

**Our forecasts are based on Realheart TAH, which is estimated to be launched in 2025 in Europe and the US.**

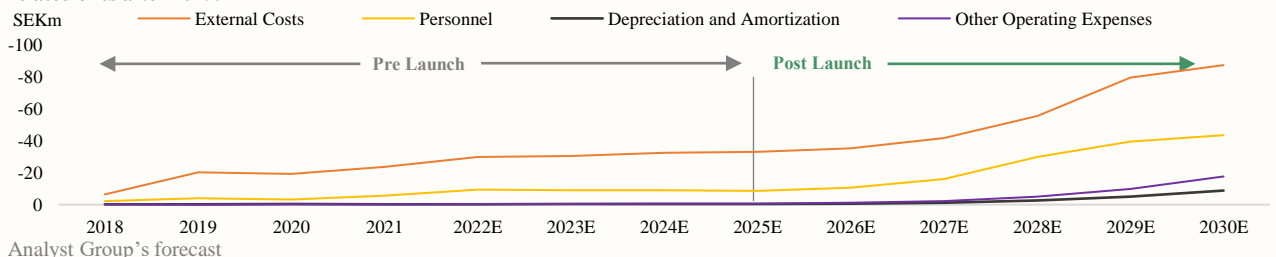
Forecasted net sales from the specified launch year



## Operating Costs Pre/Post Expected Market Launch

Until the assumed market launch in 2025, Realheart needs to conduct some OPEX investments, e.g., fine tuning of the product, clinical studies, regulatory work, etc. After market launch, operating costs are estimated to increase, where the primary drivers are assumed to be derived partly from the production of the product itself, and partly from a more comprehensive sales organization for processing hospitals in markets such as the US, Canada, and Europe.

**Operating expenses before 2025 are assumed to be related mainly to development and clinical trials, which will then shift to more sales-related ones after 2025.**



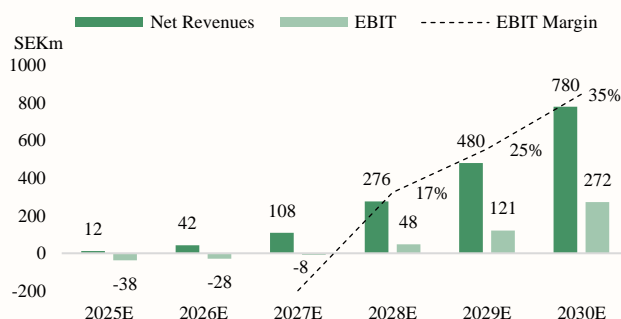
# VALUATION

The following is a summary of Analyst Group's financial forecast for Realheart after the expected market launch in 2025.

Financial forecast from estimated launch in 2025, Base scenario

Base scenario (SEKm)	2025E	2026E	2027E	2028E	2029E	2030E
Net Revenues	12	42	108	276	480	780
Other Operating Income	0	0	0	0	0	0
<b>Total Revenues</b>	<b>12</b>	<b>42</b>	<b>108</b>	<b>276</b>	<b>480</b>	<b>780</b>
COGS	-7	-23	-55	-135	-226	-351
<b>Gross Profit</b>	<b>5</b>	<b>19</b>	<b>53</b>	<b>141</b>	<b>254</b>	<b>429</b>
Gross Margin	40%	45%	49%	51%	53%	55%
Total Operating Costs	-43	-47	-61	-93	-134	-157
<b>EBIT</b>	<b>-38</b>	<b>-28</b>	<b>-8</b>	<b>48</b>	<b>121</b>	<b>272</b>
EBIT Margin	neg.	neg.	neg.	17%	25%	35%

Analyst Group's forecast



## Valuation: Base Scenario

Since the financial forecast for Realheart assumes that the Company can perform high double-digit growth after the expected market launch in 2025, the valuation is based on sales. P/S multiples for medtech companies in an early phase are generally high, due to initially low, or zero, sales. Over time, as sales increases, multiples tend to normalize in line with the company reaching a larger market share and a higher degree of maturity. Given a target multiple of P/S 5x on annual revenues of SEK276 M in 2028, this corresponds to a Market Cap of approx. SEK1,382 M. If Realheart reaches the market in 2025, this should, rather early, result in rapidly increasing sales, which would thus be considered proof that the Company has both an attractive product and also the ability to reach a significant market share. For Realheart, some steps still remain before a market launch can be realized, where the Company must pass several clinical steps, evaluations, and regulatory approvals. This constitutes a risk and, depending on the applied discount rate, which reflects the time risk from events that are several years away, and which have not yet occurred, different valuation levels are obtained. Analyst Group assumes a conservative discount rate of 18% for Realheart, which based on a company value of SEK1,382 million in 2028, results in a fundamental net present value per share today of SEK 9.4 in a Base scenario.

**SEK 9.4**  
PER SHARE  
IN A BASE  
SCENARIO

### Bull Scenario

The following is a selection of potential value drivers in a Bull scenario:

- Realheart delivers on their set agenda and results from both product development and clinical trials are positive, which contributes to a smooth process for regulatory approval and registration.
- Even before a launch is possible, Realheart has succeeded in establishing a broader network of contacts, which contributes to a faster market expansion after launch.
- Through the rights issue in September 2021, as well as additional cash injections thereafter, the cash position is still strong, but additional capital will be necessary before positive cash flows can be achieved. Given a good business development, it should be possible to raise funds at a higher valuation, which reduces the dilution effect.

Given a discount rate of 18% and a target multiple of P/S 6x on estimated sales of SEK310 M in 2028 in a Bull scenario, this yields a present value per share of SEK 12.6.<sup>1</sup>

### Bear Scenario

The following is a selection of potential factors in a Bear scenario:

- Today's prerequisites speaks for Realheart, but a lot can happen that could result in a postponed market launch, which in a Bear scenario is assumed to take place in 2027.
- The delay results in an extended period of negative cash flows, which means that the Company's need for external capital increases.
- In the event of a "worse-than-expected" development, it is conceivable that capital raises will need to be conducted with a higher valuation discount, and thus may put a downward pressure on the share price.

In a Bear scenario, a lower valuation of the share is justified, mainly motivated by the fact that the Company's work towards the planned market launch does not develop as expected. Based on the financial estimates of such scenario, a target multiple of P/S 5x and a discount rate of 18%, this yields a present value per share of SEK 2.5 in a Bear scenario.<sup>1</sup>

<sup>1</sup>See Appendix page 6 for forecasts made in the Bull and Bear scenarios, respectively.

# APPENDIX

Base scenario (SEKm)							Estimated Commercial Phase					
	2019	2020	2021	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net Revenues	0	0	0	0	0	0	12	42	108	276	480	780
Other Operating Income <sup>1</sup>	17	14	19	27	10	5	0	0	0	0	0	0
<b>Total Revenues</b>	<b>17</b>	<b>14</b>	<b>19</b>	<b>27</b>	<b>10</b>	<b>5</b>	<b>12</b>	<b>42</b>	<b>108</b>	<b>276</b>	<b>480</b>	<b>780</b>
COGS	0	0	0	0	0	0	-7	-23	-55	-135	-226	-351
<b>Gross Profit</b>	<b>17</b>	<b>14</b>	<b>19</b>	<b>27</b>	<b>10</b>	<b>5</b>	<b>5</b>	<b>19</b>	<b>53</b>	<b>141</b>	<b>254</b>	<b>429</b>
Gross Margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	40%	45%	49%	51%	53%	55%
External Costs	-20	-19	-24	-30	-30	-32	-33	-35	-42	-55	-79	-87
Personnel	-4	-3	-6	-9	-9	-9	-9	-11	-16	-30	-40	-43
Depreciation and Amortization	-0,3	-0,3	-0,2	-0,1	-0,3	-0,3	-0,4	-1	-1	-2	-5	-9
Other Operating Expenses	-0,1	-0,1	-0,1	-0,3	-0,4	-1	-1	-1	-2	-5	-10	-18
<b>EBIT</b>	<b>-7</b>	<b>-9</b>	<b>-10</b>	<b>-13</b>	<b>-30</b>	<b>-37</b>	<b>-38</b>	<b>-28</b>	<b>-8</b>	<b>48</b>	<b>121</b>	<b>272</b>
EBIT Margin	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	17%	25%	35%
P/S	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	9,4	2,7	1,0	0,4	0,2	0,1
EV/S	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	6,1	1,7	0,7	0,3	0,2	0,1
EV/EBIT	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	neg.	neg.	neg.	1,5	0,6	0,3

Bull scenario (SEKm)							Estimated Commercial Phase					
	2019	2020	2021	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net Revenues	0	0	0	0	0	0	19	75	153	310	507	1 018
Other Operating Income <sup>1</sup>	17	14	19	27	10	5	0	0	0	0	0	0
<b>Total Revenues</b>	<b>17</b>	<b>14</b>	<b>19</b>	<b>27</b>	<b>10</b>	<b>5</b>	<b>19</b>	<b>75</b>	<b>153</b>	<b>310</b>	<b>507</b>	<b>1 018</b>
COGS	0	0	0	0	0	0	-11	-40	-76	-146	-216	-407
<b>Gross Profit</b>	<b>17</b>	<b>14</b>	<b>19</b>	<b>27</b>	<b>10</b>	<b>5</b>	<b>8</b>	<b>35</b>	<b>76</b>	<b>164</b>	<b>292</b>	<b>611</b>
Gross Margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	40%	47%	50%	53%	58%	60%
External Costs	-20	-19	-23	-28	-28	-31	-32	-39	-49	-64	-89	-100
Personnel	-4	-3	-6	-8	-9	-12	-14	-21	-29	-35	-50	-60
Depreciation and Amortization	-0,3	-0,3	-0,2	-0,1	-0,3	-0,3	-0,4	-1	-2	-3	-6	-11
Other Operating Expenses	-0,1	-0,1	-0,1	-0,3	-0,4	-1	-1	-1	-3	-6	-11	-21
<b>EBIT</b>	<b>-7</b>	<b>-9</b>	<b>-9</b>	<b>-9</b>	<b>-28</b>	<b>-38</b>	<b>-39</b>	<b>-27</b>	<b>-6</b>	<b>56</b>	<b>135</b>	<b>419</b>
EBIT Margin	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	18%	27%	41%
P/S	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	5,9	1,5	0,7	0,4	0,2	0,1
EV/S	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	3,8	1,0	0,5	0,2	0,1	0,1
EV/EBIT	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	neg.	neg.	neg.	1,3	0,5	0,2

Bear scenario (SEKm)							Estimated Commercial Phase					
	2019	2020	2021	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Net Revenues	0	0	0	0	0	0	0	0	9	31	72	159
Other Operating Income <sup>1</sup>	17	14	19	27	10	8	7	5	0	0	0	0
<b>Total Revenues</b>	<b>17</b>	<b>14</b>	<b>19</b>	<b>27</b>	<b>10</b>	<b>8</b>	<b>7</b>	<b>5</b>	<b>9</b>	<b>31</b>	<b>72</b>	<b>159</b>
COGS	0	0	0	0	0	0	0	0	-6	-17	-37	-78
<b>Gross Profit</b>	<b>17</b>	<b>14</b>	<b>19</b>	<b>27</b>	<b>10</b>	<b>8</b>	<b>7</b>	<b>5</b>	<b>4</b>	<b>14</b>	<b>35</b>	<b>81</b>
Gross Margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	40%	45%	49%	51%
External Costs	-20	-19	-25	-32	-28	-31	-34	-36	-36	-38	-39	-41
Personnel	-4	-3	-7	-9	-9	-10	-10	-11	-11	-13	-17	-20
Depreciation and Amortization	-0,3	-0,3	-0,2	-0,1	-0,3	-0,3	-0,3	-0,3	-0,4	-1	-1	-2
Other Operating Expenses	-0,1	-0,1	-0,1	-0,3	-0,4	-1	-1	-1	-1	-1	-2	-3
<b>EBIT</b>	<b>-7</b>	<b>-9</b>	<b>-12</b>	<b>-14</b>	<b>-28</b>	<b>-34</b>	<b>-37</b>	<b>-42</b>	<b>-45</b>	<b>-38</b>	<b>-23</b>	<b>15</b>
EBIT Margin	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	neg.	10%
P/S	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	11,9	3,6	1,6	0,7
EV/S	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	7,8	2,4	1,0	0,5
EV/EBIT	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	neg.	neg.	neg.	4,8

<sup>1</sup> Constitutes mainly of capitalized development cost.

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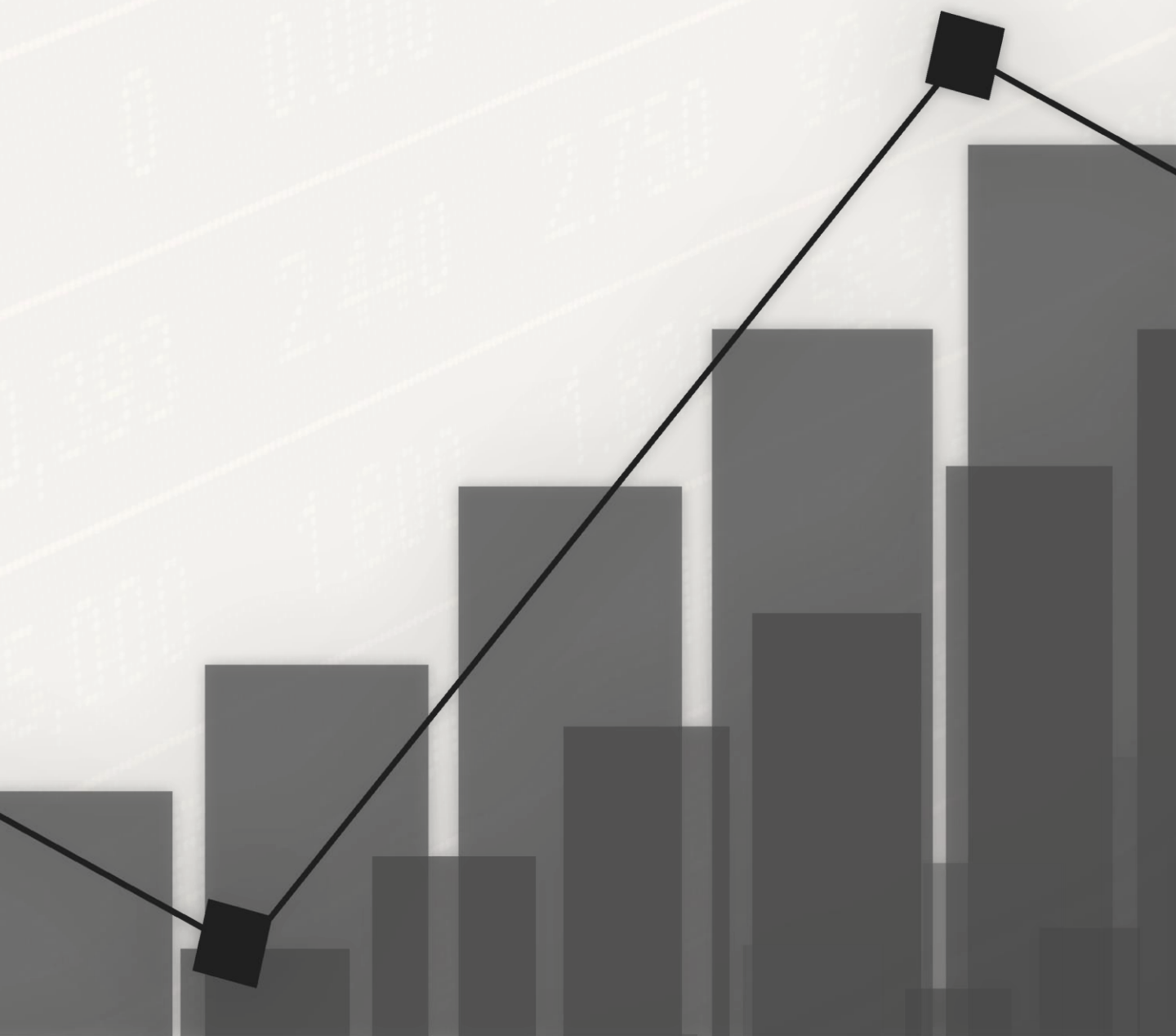
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