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# Interim Report January – June 2021

XVIVO Perfusion AB (publ)

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# XVIVO

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### Second quarter 2021 (Apr 1 - Jun 30)

- Net sales amounted to SEK 59.3 million (30.4), corresponding to an increase of 95 percent in SEK and 116 percent in local currencies. Net sales of non-durable goods amounted to SEK 56.3 million (28.0), corresponding to an increase of 101 percent in SEK and 124 percent in local currencies.
- Machine perfusion accounted for 52 percent (39) of net sales.
- Adjusted operating profit before depreciation and amortization (EBITDA) amounted to SEK 8.4 million (-1.0), corresponding to an adjusted EBITDA margin of 14 percent (-3). Reported EBITDA amounted to SEK -1.5 million (-5.5), corresponding to an EBITDA margin of -3 percent (-18).
- Adjusted operating profit (EBIT) amounted to SEK 0.6 million (-8.2). Reported EBIT amounted to SEK -9.3 million (-12.7).
- Net profit amounted to SEK -8.9 million (-16.0). Earnings per share amounted to SEK -0.31 (-0.60).
- Cash and cash equivalents at the end of the quarter amounted to SEK 311.4 million (140.0).

### Significant events during the quarter

- A 510(k) application for Kidney Assist Transport was filed with the FDA in the US.
- In the UK, NICE issued guidelines recommending EVLP as the standard arrangement for preservation of lungs.
- The number of shares and votes in XVIVO Perfusion AB (publ) increased by 33,261 following exercise of warrants under incentive program 2019/2021.

### Key ratios

| TSEK                                    | January-June<br>2021 | January-June<br>2020 | April - June<br>2021 | April - June<br>2020 | Full year<br>2020 |
|---|----------------------|----------------------|----------------------|----------------------|-------------------|
| Net sales                               | 117 588              | 76 848               | 59 263               | 30 393               | 179 861           |
| <i>Non-Durable goods</i>                | 111 120              | 72 189               | 56 259               | 28 003               | 169 425           |
| <i>Durable goods</i>                    | 6 468                | 4 659                | 3 004                | 2 390                | 10 436            |
| Machine perfusion share of net sales, % | 52                   | 34                   | 52                   | 39                   | 43                |
| Gross margin, %                         | 74                   | 76                   | 75                   | 76                   | 74                |
| <i>Non-Durable goods</i>                | 76                   | 80                   | 76                   | 81                   | 77                |
| <i>Durable goods</i>                    | 51                   | 15                   | 66                   | 17                   | 24                |
| EBITDA                                  | 9 674                | 2 098                | -1 533               | -5 452               | -15 637           |
| EBITDA (adjusted) <sup>1)</sup>         | 14 670               | 4 055                | 8 402                | -954                 | 20 172            |
| Earnings per share, SEK                 | -0,10                | -0,36                | -0,31                | -0,60                | -1,61             |
| Cash flow from operating activities     | -3 042               | 11 615               | -13 366              | 2 386                | -12 266           |

<sup>1)</sup> Adjusted for effect from cost provision attributable to cash-based incentive program for employees outside of Sweden, integration costs and cost relating to acquisition process. Net adjustment totals SEK 9.9 (-4.5) million for the quarter. Net adjustment for the period totals SEK 5.0 (-2.0) million.

### The period (Jan 1 - Jun 30)

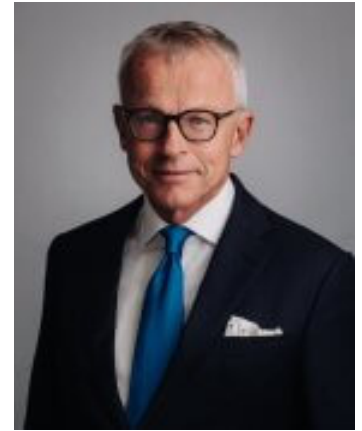
- Net sales amounted to SEK 117.6 million (76.9), corresponding to an increase of 53 percent in SEK and 68 percent in local currencies. Net sales of non-durable goods amounted to SEK 111.1 million (72.2), corresponding to an increase of 54 percent in SEK and 70 percent in local currencies.
- Machine perfusion accounted for 52 percent (34) of net sales.
- Adjusted operating profit before depreciation and amortization (EBITDA) amounted to SEK 14.7 million (4.1), corresponding to an adjusted EBITDA margin of 12 percent (5). Reported EBITDA amounted to SEK 9.7 million (2.1), corresponding to an EBITDA margin of 8 percent (3).
- Adjusted operating profit (EBIT) amounted to SEK -1.2 million (-10.7). Reported EBIT amounted to SEK -6.2 million (-12.7).
- Net profit amounted to SEK -2.9 million (-9.5). Earnings per share amounted to SEK -0.10 (-0.36).
- Cash and cash equivalents at the end of the period amounted to SEK 311.4 million (140.0).

### Significant events in the period

- An article published in The New England Journal of Medicine, shows that oxygenated perfusion of donated liver before transplantation has a significant positive impact on the outcomes after transplantation.
- First patients transplanted in the Australian heart preservation study.

# Continued recovery in the second quarter

The impact of the pandemic on hospitals varies between countries, which means that the rate at which transplant centers are returning to normal activity levels varies. The US, XVIVO's largest market, was quick to introduce an effective vaccination program, and the number of transplants for all major organs increased sharply in 2021 compared to 2020 and is now just above 2019 numbers. Other markets, such as certain European countries, started to recover later on, which has led to more patients waiting for new organs and the demand for transplants has never been higher. XVIVO's vision that "Nobody should die waiting for a new organ" has become even more relevant during the pandemic.



Dag Andersson, CEO

Total sales in the second quarter amounted to SEK 59 million, corresponding to growth of 95 percent. The positive trend in the Thoracic business area continued, and income from machine perfusion totaled SEK 20 million, an increase of 67 percent compared to the corresponding quarter 2020. In Thoracic, the North American market was a major driver with 75 percent growth in year-on-year terms. In Europe, the recovery has not been as pronounced to date, particularly within machine perfusion and in several countries the number of lung transplants has not yet recovered to 2019 levels.

In Abdominal, growth compared to corresponding quarter 2020 was as high as 126 percent. However, the second quarter of 2020 was weak. The main markets, southern and central Europe, were affected by continued lockdowns and high pressure on hospitals in the quarter, which impacted on operations and for example postponed sales of machines.

It is pleasing that XVIVO returned strong quarterly margins once again. Thoracic's gross margin on sales of non-durable goods amounted to 80 percent. Inflation is expected to increase globally and raw materials costs are expected to increase in many sectors, including ours. However, I am positive about our ability to defend Thoracic's margins and to significantly improve our margins in Abdominal over time. World-leading products should generate high margins.

With regard to our goal of launching Kidney Assist Transport on the US market, we reached an important milestone in the second quarter. Towards the end of April, we filed an 510(k) application with the FDA in the US, according to schedule. Correspondence with FDA is now underway and we are intensifying our preparations for a successful launch later in the year.

In May, we received some very positive news in the UK relating to Ex Vivo Lung Perfusion (EVLV), when the National Institute for Health and Care Excellence (NICE) issued guidelines that recommend using EVLV for the preservation of lungs. The support of EVLV is given as a standard arrangement, which is the most positive recommendation by NICE.

Another center is now actively participating in the European Heart preservation study, and a further four leading European centers have also been included - more solid evidence of the clinical relevance and significant interest in this groundbreaking study.

To conclude, I would like to highlight that XVIVO has now taken its first steps on the digital transformation journey. We have initiated a partnership with UMC Groningen where an initial pilot study will develop a method for analyzing data from liver perfusion machines. The method will provide data-based decision-making support for surgeons and transplantation teams. I am convinced that digitalization and artificial intelligence will play a key role in transplantation in many areas within a few years time, and that this will generate significant business opportunities for XVIVO.

Dag Andersson, CEO

"XVIVO's vision that "Nobody should die waiting for a new organ" has become even more relevant during the pandemic."

# This is XVIVO

Founded in 1998, XVIVO is the only medical technology company dedicated to extending the life of all major organs - so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of transplantation medicine. XVIVO is headquartered in Gothenburg, Sweden, and has offices and research sites on two continents. The company is listed on Nasdaq Stockholm.

## Vision

Nobody should die waiting for a new organ.

## Purpose

We believe in an extended life of donated organs.

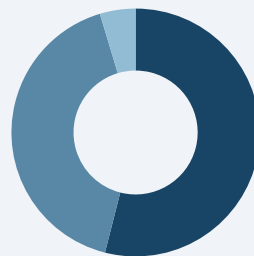
## Target

Establish machine perfusion as a standard method for preserving, evaluating and transporting donated organs before transplantation.

# >160,000

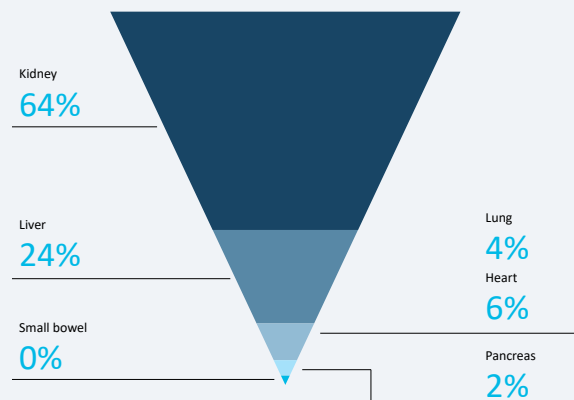
Organs transplanted per year, representing ~10% of the need\*

\*WHO estimate



NET SALES PER GEOGRAPHICAL REGION IN THE QUARTER

- Americas (54%)
- EMEA (41%)
- APAC (5%)



## Strategic focus areas

### THE WORLD LEADER IN ALL MAJOR ORGANS

XVIVO will build on its world-leading position in lung transplantation and develop the offer to include technology platforms and solutions for all four major organs: lungs, heart, kidney and liver.

### CUSTOMER-DRIVEN INNOVATION

To develop XVIVO commercially, we will bring innovation and progress even closer to our customers. Our established relationships with clinics, scientists and opinion formers are an important asset in this context.

### HIGH-PERFORMING ORGANIZATION

XVIVO has developed its leading research and development competences and capacity over many years. The next phase consists of building a more efficient organization to ensure the successful commercialization of our entire product portfolio.

### COMMERCIAL POTENTIAL

XVIVO's commercial ability will be developed. Our active pricing strategy will be driven by clinical relevance and we will expand into new geographical markets.

### OPERATIONAL STRENGTH

Our commercial potential is closely associated with our operational strength. A clearer operational focus will improve cost efficiency and delivery reliability.

# Compilation of Net Sales and EBITDA

| SEK Thousands   | January-June<br>2021 | January-June<br>2020 | April-June<br>2021 | April-June<br>2020 | January-<br>December<br>2020 |
|---|----------------------|----------------------|--------------------|--------------------|------------------------------|
| Net Sales non-Durable Goods   | 111 120              | 72 189               | 56 259             | 28 003             | 169 425                      |
| Net Sales Durable Goods   | 6 468                | 4 659                | 3 004              | 2 390              | 10 436                       |
| <b>Net Sales Total</b>  | <b>117 588</b>       | <b>76 848</b>        | <b>59 263</b>      | <b>30 393</b>      | <b>179 861</b>               |
| Cost of Goods non-Durable Goods                                       | -27 174              | -14 415              | -13 707            | -5 316             | -38 980                      |
| Cost of Goods Durable goods   | -3 187               | 3 949                | -1 009             | -1 975             | -7 906                       |
| Cost of Goods Total   | -30 361              | -18 364              | -14 716            | -7 291             | -46 886                      |
| Gross income non-Durable Goods  | 83 946               | 57 774               | 42 552             | 22 687             | 130 445                      |
| Gross margin non-Durable Goods, %                                     | 76%                  | 80%                  | 76%                | 81%                | 77%                          |
| Gross income Durable Goods  | 3 281                | 710                  | 1 995              | 415                | 2 530                        |
| Gross margin Durable Goods, %   | 51%                  | 15%                  | 66%                | 17%                | 24%                          |
| Gross income Total  | 87 227               | 58 484               | 44 547             | 23 102             | 132 975                      |
| Gross margin Total, %   | 74%                  | 76%                  | 75%                | 76%                | 74%                          |
| Selling expenses  | -40 309              | -27 200              | -20 613            | -12 360            | -59 899                      |
| Administrative expenses   | -25 638              | -10 717              | -14 605            | -5 069             | -30 342                      |
| Research and development expenses                                     | -29 563              | -29 059              | -14 034            | -12 186            | -56 178                      |
| Other operating revenues and expenses <sup>1)</sup>                   | 2 116                | -4 194               | -4 645             | -6 196             | -32 231                      |
| <b>Operating Income</b>   | <b>-6 167</b>        | <b>-12 686</b>       | <b>-9 350</b>      | <b>-12 709</b>     | <b>-45 675</b>               |
| Amortization and depreciation cost of goods sold                      | -169                 | -431                 | -90                | -216               | -462                         |
| Depreciation administrative expenses                                  | -1 646               | -1 520               | -266               | -757               | -3 154                       |
| Amortization of research and development expenses                     | -11 561              | -10 025              | -5 627             | -4 993             | -21 133                      |
| Depreciation other operative expenses                                 | -2 465               | -2 808               | -1 834             | -1 291             | -5 289                       |
| <b>EBITDA (Operating income before depreciation and amortization)</b> | <b>9 674</b>         | <b>2 098</b>         | <b>-1 533</b>      | <b>-5 452</b>      | <b>-15 637</b>               |
| EBITDA, %   | 8%                   | 3%                   | -3%                | -18%               | -9%                          |
| <b>EBITDA (adjusted) <sup>2)</sup></b>                                | <b>14 670</b>        | <b>4 055</b>         | <b>8 402</b>       | <b>-954</b>        | <b>20 172</b>                |
| EBITDA (adjusted), %  | 12%                  | 5%                   | 14%                | -3%                | 11%                          |

<sup>1)</sup> See note 4 for "Other operating revenues and expenses"

<sup>2)</sup> Adjusted for effect from cost provision attributable to cash-based incentive program for employees outside of Sweden, integration costs and cost relating to acquisition process. Net adjustment totals SEK 9.9 (-4.5) million for the quarter. Net adjustment for the period totals SEK 5.0 (-2.0) million.



# Summary

## The quarter April - June 2021

### Net sales and income

We can conclude that the Covid-19 pandemic continued to affect the number of transplants globally in the second quarter of 2021. On several markets, available hospital resources have continued to focus on caring for Covid-19 patients, which means that the number of transplanted organs in some markets has decreased, and more patients are now waiting for a new organ.

Net sales increased by 95 percent during the quarter, amounting to SEK 59.3 million (30.4). This corresponds to an increase of 116 percent in local currencies. Net sales of non-durable goods increased by 101 percent, amounting to SEK 56.3 million (28.0). The increase corresponds to 124 percent in local currency.

Organic growth amounted to 82 percent in local currencies. Acquired growth amounted to 34 percent in local currencies.

Machine perfusion accounted for 52 percent (39) of net sales. Static preservation and other sales (revenue from service and training etc.) accounted for the remaining part of sales.

Gross margin for the quarter amounted to 75 percent (76) and gross margin for non-durable goods amounted to 76 percent (81). The decrease is explained by the fact that the comparison quarter does not include the Abdominal business area, which has lower margins than Thoracic.

Operating profit before depreciation and amortization (EBITDA) profit was negatively affected by cash-based incentive programs for employees outside Sweden by SEK -3.9 million and was charged with integration costs of SEK -2.7 million. Furthermore, the quarter also included costs of SEK -3.4 million attributable to an acquisition process, which the company chose to cancel after due diligence. Adjusted for these items totaling SEK -9.9 million (-4.5), adjusted EBITDA amounts to SEK 8.4 million (-1.0), corresponding to an EBITDA margin of 14 percent (-3). Reported EBITDA amounted to SEK -1.5 million (-5.5), corresponding to an EBITDA margin of -3 percent (-18).

Operating income (EBIT) adjusted for the above-mentioned items amounted to SEK 0,6 million (-8.2). Reported EBIT amounted to SEK -9.4 million (-12.7).

Selling expenses in relation to sales amounted to 35 percent (41) for the quarter. R&D expenses amounted to 24 percent (40) of sales. Administrative expenses amounted to 25 percent (17) of sales. The company received US government support totaling SEK 3.8 million, which has been recognized as reduced personnel expenses mainly in selling expenses and R&D.

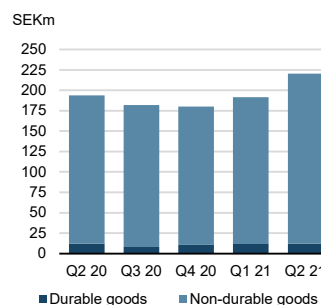
The quarter was charged with costs for the integration of Organ Assist. The acquisition was consolidated into XVIVO on October 1, 2020, and since then, the focus has primarily been on integrating the sales and administration functions. During the second quarter, integration costs affected sale expenses by SEK 1.3 million (-) and administration expenses by SEK 1.4 million (-). Work is underway to centralize goods distribution to XVIVO's office in the Netherlands. The work is expected to be completed at the end of the third quarter and the integration costs from the acquisition are subsequently expected to cease.

Other operating income and operating expenses amounted to SEK -4.6 million (-6.2) during the quarter. The item primarily consists of costs from the cash-based incentive program for employees abroad of SEK -3.9 million. The remainder primarily consists of currency conversion effects and depreciation. See Note 4 for more information.

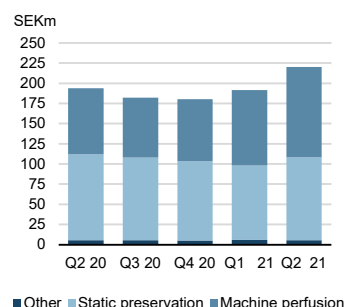
Net financial income and expenses for the quarter amounted to SEK -1.4 million (-6.0). This was mainly due to negative currency conversion effects relating to the Group's cash and cash equivalents.

During the quarter, SEK 19.2 million (13.3) of development expenditures were capitalized as intangible assets. Development expenditure in all material respects relates to expenditure in R&D projects with the aim of obtaining regulatory approvals in the US and Europe. Amortization of capitalized development expenses amounted to SEK 4.9 million (3.8) during the quarter, of which SEK 3.9 million (3.8) is attributed to regulatory approvals for the company's products within lung transplantation. The remainder relates to depreciation of R&D projects within the abdominal business.

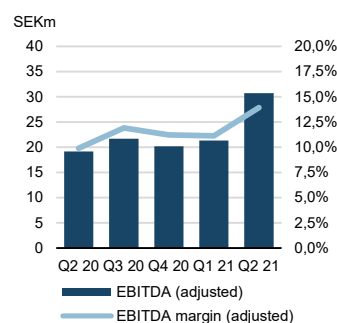
Net sales per segment (R12)



Net sales per product category (R12)



EBITDA och EBITDA-margin (adjusted, R12)



## Cash flow

Cash flow from operating activities during the quarter amounted to SEK -13.4 million (2.4) and was marked by one-time items such as costs for acquisition process and payment of cash-based incentive programs for foreign employees. Furthermore, the capital tied-up in inventories has increased as part of securing the availability of the company's lung and kidney transplant products and the upcoming product launch of Kidney Assist Transport. Cash flow from investing activities amounted to SEK -22.8 million (-13.9), of which SEK -20.3 million (-13.5) was invested in intangible assets and SEK -2.5 million (-0.4) was invested in tangible assets. Cash flow from financing activities amounted to net SEK 0.1 million (-0.1). Exchange rate differences in the quarter had a negative effect on the cash flow by SEK -2.8 million (-7.0). Cash and cash equivalents at the end of the quarter amounted to SEK 311.4 million (140.0).

## Significant events during the quarter

### 510(k) application for Kidney Assist Transport filed with the FDA in the US

In the second quarter, XVIVO filed a 510(k) application with the FDA for Kidney Assist Transport, with the aim of obtaining regulatory approval for product sales on the US market later in 2021.

Kidney Assist Transport is XVIVO's transportable system for kidney preservation. The system enables isolated hypothermic oxygen perfusion of donated kidneys during transport between donor and recipient in connection with kidney transplants.

Following the announcement of XVIVO's acquisition of Organ Assist B.V. on 1 October 2020, the filing of a 510(k) application for Kidney Assist Transport is an important milestone in XVIVO's strategy of establishing a commercial presence in abdominal transplantation in the US. In 2019, approximately 62,000 kidney transplants from deceased donors were carried out globally. The US is the largest market by some margin, with approximately 17,500 kidney transplants from deceased donors in 2019. There are more than 90,000 patients on the waiting list in the US, so demand for organs for transplantation by far exceeds supply.

### National Institute for Health and Care Excellence (NICE) supports EVLP

In the UK, the National Institute for Health and Care Excellence (NICE) has issued interventional procedure guidance recommending the use of Ex Vivo Lung Perfusion (EVLP) for preservation of lungs. The support of EVLP is given as standard arrangement, which is the most positive recommendation by NICE, and EVLP is described as a method that enables longer and better preservation of donated lungs.

The NICE guidelines are evidence-based recommendations that guide decisions in health, public health and social care in the UK and Wales. The interventional procedure program assesses the safety and efficacy of interventional procedures.

Today only one in five donated lungs are used for transplant in the UK. The lack of deceased donor lungs leads to deterioration and death in up to 30 percent of patients awaiting a lung transplant. There are currently 257 patients waiting for a lung transplant in the UK and the average wait is 18 months.

### Change in number of shares and votes in XVIVO Perfusion AB (publ)

The number of shares and votes in XVIVO Perfusion AB (publ) increased by 33,261 shares and votes in June 2021 as a result of the utilization of warrants under the company's incentive scheme 2019. As of 30 June 2021, there were a total of 28,752,397 shares and votes in the company.

## The period January - June 2021

### Net sales and income

We can conclude that the Covid-19 pandemic is continuing to affect the number of transplantations globally in 2021. Available hospital resources have largely focused on caring for Covid-19 patients and thus the number of transplanted organs in several markets has decreased and more patients are now waiting for a new organ.

Net sales increased by 53 percent in the period, amounting to SEK 117.6 million (76.9). That corresponds to an increase of 68 percent in local currencies. Net sales of non-durable goods increased by 54 percent, amounting to SEK 111.1 million (72.2). The increase corresponds to 70 percent in local currency.

Organic growth amounted to 38 percent in local currencies. Acquired growth amounted to 31 percent in local currencies.

Machine perfusion accounted for 52 percent (34) of net sales. Static preservation and other sales (revenue from service and training etc.) accounted for the remaining part of sales.

Gross margin for the period amounted to 74 percent (76) and gross margin for non-durable goods amounted to 76 percent (80). The decrease is explained by the fact that the comparative period does not include the Abdominal business area, where the margins are lower than Thoracic.

Operating profit before depreciation and amortization (EBITDA) was positively affected by the dissolution of a cost provision for cash-based incentive programs for employees outside Sweden of SEK 3.2 million and was charged with integration costs by SEK -4.8 million. Furthermore, the quarter also included costs of SEK -3.4 million attributable to an acquisition process, which the company chose to cancel after due diligence. Adjusted for these items by a net SEK -5.0 million (-2.0), EBITDA amounts to SEK 14.7 million (4.1), corresponding to an adjusted EBITDA margin of 12 percent (5). Reported EBITDA amounted to SEK 9.7 million (2.1), corresponding to an EBITDA margin of 8 percent (3).

Operating income (EBIT) adjusted for the above-mentioned items amounted to SEK -1.2 million (-10.7). Reported EBIT amounted to SEK -6.2 million (-12.7).

Selling expenses as a proportion of sales amounted to 34 percent (35) in the period. R&D expenses amounted to 25 percent (38) of sales. Administrative expenses amounted to 22 percent (14) of sales. The company received US government support totaling SEK 3.8 million, which has been recognized as reduced personnel expenses mainly in selling expenses and R&D.

The period was charged with costs for the integration of Organ Assist. The acquisition was consolidated into XVIVO on October 1, 2020 and since then, the focus has primarily been on integrating the sales and administrative functions. During the period, integration costs affected sale expenses by SEK 2.3 million (-) and administration expenses by SEK 2.5 million (-).

Other operating income and operating expenses amounted to SEK 2.1 million (-4.2) in the period. The item primarily consists of positive effects from the cash-based incentive program for employees abroad of SEK 3.2 million. The remainder primarily consists of currency conversion effects and depreciation. See Note 4 for more information.

Net financial income and expenses for the period amounted to SEK 3.7 million (0.5). The positive contribution is mainly due to positive currency conversion effects relating to the Group's cash and cash equivalents.

During the period, SEK 35.2 million (28.5) of development expenditure were capitalized as intangible assets. Development expenditure essentially relate to R&D expenses in connection with obtaining regulatory approvals in the US and Europe. Amortization of capitalized development expenses amounted to SEK 10.1 million (7.8) in the period, of which SEK 7.8 million (7.8) was attributed to regulatory approvals for the company's products in lung transplantation. The remainder relates to depreciation of R&D projects in the Abdominal business area.

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Net sales

**SEK 118  
million**

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Gross margin

**74%**

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Adjusted EBITDA

**12%**



## Cash flow

Cash flow from operating activities in the period amounted to SEK -5.0 million (11.6), primarily due to an increase in capital tied up in inventories and payment of operating liabilities. One-time items such as costs for acquisition process and payment of cash-based incentive programs for foreign employees have also affected the cash flow. Cash flow from investing activities amounted to SEK -42.3 million (-29.7), of which SEK -37.1 million (-28.9) was invested in intangible assets and SEK -5.2 million (-0.8) was invested in tangible assets. Cash flow from financing activities amounted to net SEK -0.9 million (-1.6). Exchange rate differences in the period had a positive cash flow effect of SEK 3.5 million (-0.2). Cash and cash equivalents at the end of the period amounted to SEK 311.4 million (140.0).

## Financing

XVIVO's operations shall be conducted with a sustainable and efficient capital structure. The company's equity/assets ratio is strong and amounted to 88 percent (92) at the end of the period. The company's total credit facility consists of an overdraft facility, which amounted to SEK 30 million (30) at the end of the period, of which SEK 0.0 million (0.0) was utilized.

## Significant events in the reporting period

### A study published in The New England Journal of Medicine shows significant advantages with oxygenated, cold machine perfusion prior to liver transplantation

An article in The New England Journal of Medicine shows that oxygenated perfusion of donated liver before transplantation has a significant positive impact on post-transplantation outcomes. The article presents the results from a study performed by a large international consortium of liver transplant centers led by Professor Robert Porte, liver surgeon at the University Medical Center Groningen in the Netherlands. Transplant centers in the Netherlands, Belgium and United Kingdom participated.

Livers from 156 high risk donors (Donation after Circulatory Death) were included in the study and randomized to either the current treatment regime, static cold storage or 2 hours of cold oxygenated machine perfusion after static cold storage. The main purpose of the study was to investigate the presence of biliary complications within six months after transplantation.

This study demonstrated a significant benefit when oxygenated machine perfusion was used. During the follow-up period only 6 percent of patients that received a machine perfused liver developed biliary complications, compared to 18 percent in the static cold storage group. Furthermore, the risk of circulatory instability in these patients and the incidence of early graft dysfunction reduced by nearly half.

The risk of complications for patients transplanted with a liver donated after circulatory arrest are greater than if the liver comes from a donation after brain death. Because of this, many transplant centers are hesitant to accept donor livers of this kind. This is especially true in the USA where few livers are used from donors after circulatory death compared to countries such as the Netherlands, Belgium and the UK. The machine perfusion technology used in the trial sharply decreases complications after transplant and has the potential to increase the number of transplanted patients.

The Liver Assist device used for oxygenated perfusion in the trial is CE-marked. XVIVO intends to submit an application for regulatory approval of the device with the FDA before the end of 2021.

### First patients transplanted in Australian heart preservation study

Approximately 7,500 heart transplants are performed globally each year. The absence of blood flow and oxygen during donor heart transport may translate into poor patient outcomes after transplantation. The period a donated heart can be stored on ice outside the body is limited to four hours. The detrimental effects of a prolonged out-of-body time of the donor heart is reflected in an increased rate of complications and impaired survival after transplantation.

The first patients in an investigator-initiated heart preservation study using XVIVO's technology were transplanted during the first quarter of 2021. The study will include Australian and New Zealand transplant centers and is set to investigate whether the novel preservation technology can safely double the transport time for donor hearts beyond the current limit of 4 hours.

XVIVO's innovative preservation method has been developed alongside Professor Stig Steen. The method includes a machine that supplies the cooled heart with continuous circulation of a propriety oxygenated solution during transport. A safety study published in Nature Communications in June 2020 showed that the use of the heart preservation technology developed by Professor Stig Steen is a safe method for preservation of human hearts.

# Business area development

XVIVO's operations are conducted in two business areas: Thoracic (lung and heart transplantation) and Abdominal (liver and kidney transplantation). Both business areas conduct commercial and R&D activities.

## Thoracic

Business area Thoracic consists of XVIVO's lung and heart transplantation business. In lung transplantation, the company's product Perfadex® Plus has a market share of approximately 90 percent in traditional static preservation of lungs. The company's products for warm perfusion, XPS™ and STEEN Solution™, have market approval in all major markets and in 2019, they were the first products to receive FDA approval for warm perfusion of marginal lungs. In heart transplantation, XVIVO's products are in a clinical study phase. Some sales take place in heart transplantation - mainly in pre-clinical xeno-transplantation.

### Summary

| SEK Thousands     | January-June<br>2021 | January-June<br>2020 | April-June<br>2021 | April-June<br>2020 |
|-------------------|----------------------|----------------------|--------------------|--------------------|
| Net sales         | 96 288               | 76 848               | 49 870             | 30 393             |
| Non-Durable goods | 92 808               | 72 189               | 49 045             | 28 003             |
| Durable goods     | 3 480                | 4 659                | 825                | 2 390              |
| Gross margin, %   | 79                   | 76                   | 80                 | 76                 |
| Non-Durable goods | 80                   | 80                   | 80                 | 81                 |
| Durable goods     | 43                   | 15                   | 82                 | 17                 |

### The quarter April - June 2021

Net sales increased in the quarter compared to the corresponding period in the previous year, amounting to SEK 49.9 million (30.4). In local currencies, this represented growth of 82 percent. Net sales of non-durable goods increased by 75 percent, amounting to SEK 49.0 million (28.0). This was mainly due to strong recovery on the US market. In Europe, the recovery has not been as clear to date. Extensive lockdowns and continued pressure on hospitals in several European countries have temporarily restricted sales opportunities.

Machine perfusion accounted for 40 percent (39) of net sales. Static preservation and other sales accounted for the remainder of net sales.

Gross margin was 80 percent (76) in the quarter. Gross margin for non-durable goods was 80 percent (81).

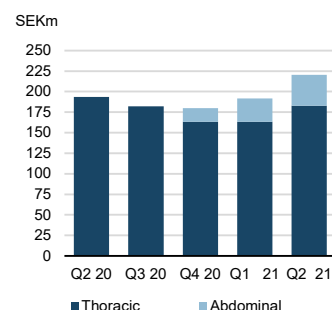
### The period January - June 2021

Net sales increased in the period compared to the corresponding period in the previous year, amounting to SEK 96.3 million (76.9). In local currencies, this represented growth of 38 percent. Net sales of non-durable goods increased by 29 percent, amounting to SEK 92.8 million (72.2). In local currencies, this represented growth of 42 percent. During the period, one XPS machine was sold to a clinic in Louisville, US.

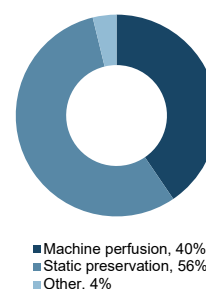
Machine perfusion accounted for 41 percent (34) of net sales. The increase was primarily driven by a recovery at the established EVLP-clinics in the US. XVIVO's ten largest customers in the US are all returning growth in year-on-year terms. Static preservation and other sales accounted for the remainder of net sales.

Gross margin for the period was 79 percent (76). Gross margin excluding non-durable goods was 80 percent (80).

Net sales per business area (R12)



Net sales per product category, Thoracic (Q2)



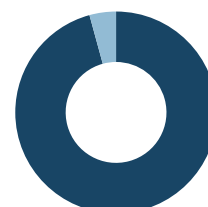
## Abdominal

The Abdominal business area consists of XVIVO's business within liver and kidney transplantation. XVIVO offers machine perfusion products for both organs. The products are primarily sold in Europe at present, but also on smaller markets outside North America.

### Summary

| SEK Thousands            | January-June<br>2021 | January-June<br>2020 | April-June<br>2021 | April-June<br>2020 |
|--------------------------|----------------------|----------------------|--------------------|--------------------|
| Net sales                | 21 300               | -                    | 9 393              | -                  |
| <i>Non-Durable goods</i> | 18 312               | -                    | 7 214              | -                  |
| <i>Durable goods</i>     | 2 988                | -                    | 2 179              | -                  |
| Gross margin, %          | 52                   | -                    | 52                 | -                  |
| <i>Non-Durable goods</i> | 50                   | -                    | 50                 | -                  |
| <i>Durable goods</i>     | 60                   | -                    | 60                 | -                  |

Net sales per product category, Abdominal (Q2)



### The quarter April - June 2021

In Abdominal, where the customer base is currently largely focused on certain southern and central European key markets, the pandemic continued to significantly impact operations in the second quarter. Extensive lockdowns and continued pressure on hospitals in several European countries has temporarily restricted sales and led to postponed machine sales, for example.

Net sales in the quarter amounted to SEK 9.4 million (-). Net sales of non-durable goods amounted to SEK 7.2 million (-). Because XVIVO's abdominal operations were acquired in the fourth quarter of 2020, there are no comparative figures for the Group for the second quarter of 2021. The underlying business showed organic growth of 126 percent. Machine perfusion accounted for 96 percent (-) of net sales.

Gross margin for non-durable goods was 50 percent (-) in the quarter.





### The period January - June 2021

Net sales amounted to SEK 21.3 million (-) in the period. Net sales of non-durable goods amounted to SEK 18.3 million (-). Because XVIVO's abdominal operations were acquired in the fourth quarter 2020, there are no comparative figures for the Group for the period January - June 2021. The underlying business returned organic growth of 64 percent. Machine perfusion accounted for 96 percent (-) of net sales.


Gross margin for non-durable goods was 50 percent (-) in the period. Price increases were implemented according to plan during the first quarter, but the positive effect on gross profit margin was temporarily absorbed by increased purchase prices. A change of supplier is in progress and the gross margin is estimated to be strengthened after receiving regulatory approval as the new products have a lower manufacturing cost.

# R&D Portfolio

## Development projects

| Project   | Description   | Status   |
|---|---|--|
| <b>Heart transplantation</b><br>   | <p>The primary restriction on the number of heart transplants possible today comes from the number of available, usable donated organs based on current technology, in combination with the period that a donated heart can be outside the body. In collaboration with Professor Stig Steen, XVIVO has developed a total solution consisting of fluids and machinery that better preserve the function of the donated heart during transport, which contributes to improved outcomes after heart transplantation. In the ongoing clinical trials, patients are selected by lottery to be transplanted either with donated hearts transported by XVIVO's method or by the conventional ice-box method.</p> | <p>XVIVO is developing a program of clinical multicenter studies. These will form the basis for an application for regulatory approval for the products on all major global markets. In Europe, five clinics are currently actively enrolling patients in the XVIVO study. A further 4-6 clinics are in the start-up phase. Several centers contacted XVIVO requesting to participate in the second quarter 2021. A similar multicenter study is also at the planning stage in the US, where the company received 'breakthrough device designation' by the FDA. In addition to the studies carried out by XVIVO, another Swedish research-initiated study is also underway using XVIVO's technology. A research-initiated study has also started in Australia during the first quarter 2021.</p> |
| <b>Kidney transplantation</b><br> | <p>Like for other organs, there is a shortage of transplantable kidneys. Studies have demonstrated that transport of kidneys with ongoing perfusion improves post-transplant outcomes in many cases. The optimal method for transporting donated kidneys is being studied in several ongoing international trials.</p>  | <p>The results of an international high-quality study were published in The Lancet in the fourth quarter 2020. The study demonstrated significant benefits for the recipient when the kidney is transported perfused with an oxygenated solution. This technology is unique to XVIVO. The company filed an application for regulatory approval in the US in the second quarter 2021. The combination of new perfusion technology and solutions will be the focus of future research in the organ field.</p>  |
| <b>Liver transplantation</b><br> | <p>Like for other organs, there is a shortage of transplantable livers. By preserving and evaluating the function of donated liver optimally, more organs with good function are potentially available for transplant. Studies show that oxygenated perfusion of liver before transplantation reduces the risk of serious complications in some cases.</p>  | <p>The results of a study published in The New England Journal of Medicine in the first quarter 2021 demonstrate significant benefits of oxygenated machine perfusion of liver prior to transplantation in post-cardiac donation (DCD). XVIVO's technology was used in the study and XVIVO is the only market operator offering this unique technology. The work associated with applying for regulatory approval for the company's products in the US will be intensified during the year. Future research in the field will focus on the combination of new perfusion technology and solutions.</p>  |
| <b>PrimECC®</b><br>              | <p>PrimECC® is a fluid developed in collaboration with Professor Stig Steen intended for use in heart-lung machines. Before connecting the cardiopulmonary machine to a patient, the machine must be filled with fluid, usually simple saline solutions. In 2016 and 2017, a randomized clinical trial on 80 patients indicated reduced side effects related to the use of cardiac lung machine when using PrimECC®.</p>  | <p>XVIVO has patents for PrimECC® on key markets in the US, EU, China, and Japan. Several hundred thousand heart surgeries are performed each year, which means considerable sales potential if good clinical results can be demonstrated. The company is awaiting product launch until the results of the current expanded study has been analyzed. In addition to Sahlgrenska University Hospital, Rigshospitalet in Copenhagen was recruited as an additional study center in the first quarter, and preparations are underway to also include Rikshospitalet in Oslo in the study.</p>   |

## Research projects

| Project  | Description  | Status  |
|--|--|---|
| <b>Xeno-transplantation</b><br> | <p>Xeno-transplantation involves the use of non-human organs in transplantation. The method is currently at the research stage for several organs.</p> | <p>XVIVO's technology for preserving heart function is currently used continuously by two world-leading research teams and has been crucial for attaining successful outcomes when genetically modified hearts from pig are transplanted into primates.</p> |

# Other information

## Sustainability

Everyone who works at XVIVO is dedicated to our vision that "nobody should die waiting for a new organ" and we are proud that our innovations help give patients the opportunity to live longer and better lives. For more than two decades we have focused on developing, manufacturing and marketing technology that contributes to making more donated organs available for transplant.

XVIVO's Code of Conduct is our primary sustainability policy. This includes guidelines for business principles, human rights and working principles. For more detailed information relating to our sustainability work, see the Company's Annual Report for 2020 which, alongside the Code of Conduct, is available at [www.xvivogroup.com](http://www.xvivogroup.com).

## Organization and staff

XVIVO employs 90 people, of which 41 women and 49 men. Of these, 42 people are employed in Sweden and 48 outside Sweden. The head office is located in Gothenburg, Sweden and our subsidiaries are located in Lund, Sweden, Denver, USA and Groningen, The Netherlands XVIVO also has employees based in several other countries in Europe, the US, China and Australia.

## Related party transactions

There were no transactions with related parties during the period.

## Risk management

XVIVO works continuously to identify, evaluate, and manage risks in different systems and processes. Risk analyses are carried out continuously regarding normal operations and in connection with activities that are outside XVIVO's regular quality system.

The market risks that are deemed to have a particular impact on XVIVO's future progress are linked to the availability of financial and medical resources in clinics around the world. Operational risks are risks that limit or prevent XVIVO from developing, manufacturing and selling qualitative, efficient and safe products. The number of organ transplants is marginally affected by seasonal effects. Mainly in new treatment methods such as hot perfusion of lungs, slightly less activity occurs during the summer months due to the fact that training and learning are allowed to stand back during the summer holidays. Legal and regulatory risks may arise from changes in legislation or policy decisions that may affect the Group's ability to conduct or develop the business. Financial risks include exchange rate risks.

The crucial strategic risks and operative risks for the Group is to be found in the Administration report as part of the Annual report for 2020, which is available at [www.xvivogroup.com](http://www.xvivogroup.com).

## Outlook

The extent to which the Covid-19 pandemic will affect our sales and clinical trials during the remainder of 2021 is largely determined by the speed of the vaccine roll-out globally, and how fast intensive care operations on the company's main markets in the US and Europe return to normal capacity. Transplantation is a life-sustaining treatment and transplants are prioritized by health authorities around the world and for this reason, the company estimates that the number of transplants, and thus demand for XVIVO's products, will continue to increase long-term.

In 2021, XVIVO will continue to focus sharply on regulatory applications, clinical studies and product development in all major organ areas. The company aims to obtain regulatory approval for Kidney Assist Transport in the US in the fourth quarter. For Liver Assist, the aim is to file an application for deNovo approval with the FDA towards the end of 2021. In heart transplantation, the goal is to take significant steps forward in the clinical multi-center studies in Europe, the US and Australia. The PrimECC® study is expected to accelerate in line with more clinics being included.



## Significant events after the reporting period

No events occurred after the end of the reporting period that affect the assessment of the financial information in this report.

The Board of Directors and CEO hereby give their assurance that the Interim Report presents an accurate summary of the Group's and Parent Company's operations, position and results of operations and describes the material risks and uncertainty factors the Parent Company and the companies included in the Group face.

Gothenburg, July 13, 2021

Gösta Johannesson  
Chairman of the Board

Camilla Öberg  
Board member

Folke Nilsson  
Board member

Yvonne Mårtensson  
Board member

Lars Henriksson  
Board member

Lena Höglund  
Board member

Dag Andersson  
CEO

This report has not been audited by the company's auditors.

*This is a translation of the Swedish version of the report. When in doubt, the Swedish wording prevails.*

This information is information that XVIVO Perfusion AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Market Securities Act. The information was submitted for publication, through the agency of the contact person set out below on July 13, 2021 at 7.30 am.



### Financial calendar

- Interim Report January-September 2021:  
Thursday, October 28, 2021
- Year-end Report 2021:  
Thursday, January 27, 2022
- Interim Report January-March 2022:  
Monday, April 25, 2022
- Interim Report January-June 2022:  
Wednesday, July 13, 2022



### Conference call

CEO Dag Andersson and CFO Kristoffer Nordström will present the report in a conference call at 2.00 p.m. CET on Tuesday, July 13, 2021.

Telephone SWE: +46 (0)8 566 426 51  
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# Financial statements

## Condensed Consolidated Statement of Net Income

| SEK Thousands   | January-June<br>2021 | January-June<br>2020 | April-June<br>2021 | April-June<br>2020 | January-<br>December<br>2020 |
|---|----------------------|----------------------|--------------------|--------------------|------------------------------|
| Net sales   | 117 588              | 76 848               | 59 263             | 30 393             | 179 861                      |
| Cost of goods sold  | -30 361              | -18 364              | -14 716            | -7 291             | -46 886                      |
| <b>Gross income</b>   | <b>87 227</b>        | <b>58 484</b>        | <b>44 547</b>      | <b>23 102</b>      | <b>132 975</b>               |
| Selling expenses  | -40 309              | -27 200              | -20 613            | -12 360            | -59 899                      |
| Administrative expenses   | -25 638              | -10 717              | -14 605            | -5 069             | -30 342                      |
| Research and development expenses                                     | -29 563              | -29 059              | -14 034            | -12 186            | -56 178                      |
| Other operating revenues and expenses <sup>1)</sup>                   | 2 116                | -4 194               | -4 645             | -6 196             | -32 231                      |
| <b>Operating income</b>   | <b>-6 167</b>        | <b>-12 686</b>       | <b>-9 350</b>      | <b>-12 709</b>     | <b>-45 675</b>               |
| Financial income and expenses   | 3 670                | 503                  | -1 411             | -6 047             | -11 588                      |
| <b>Income after financial items</b>                                   | <b>-2 497</b>        | <b>-12 183</b>       | <b>-10 761</b>     | <b>-18 756</b>     | <b>-57 263</b>               |
| Taxes   | -411                 | 2 708                | 1 820              | 2 738              | 13 528                       |
| <b>Net income</b>   | <b>-2 908</b>        | <b>-9 475</b>        | <b>-8 941</b>      | <b>-16 018</b>     | <b>-43 735</b>               |
| <b>Attributable to</b>  |                      |                      |                    |                    |                              |
| Parent Company's shareholders   | -2 908               | -9 475               | -8 941             | -16 018            | -43 735                      |
| Earnings per share, SEK   | -0,10                | -0,36                | -0,31              | -0,60              | -1,61                        |
| Earnings per share, SEK <sup>2)</sup>                                 | -0,10                | -0,36                | -0,31              | -0,60              | -1,60                        |
| Average number of outstanding shares                                  | 28 723 201           | 26 600 496           | 28 727 266         | 26 600 496         | 27 171 352                   |
| Average number of outstanding shares <sup>2)</sup>                    | 29 097 201           | 26 600 496           | 29 101 266         | 26 600 496         | 27 354 518                   |
| Number of shares at closing day                                       | 28 752 397           | 26 600 496           | 28 752 397         | 26 600 496         | 28 719 136                   |
| Number of shares at closing day <sup>2)</sup>                         | 29 126 397           | 26 600 496           | 29 126 397         | 26 600 496         | 29 444 136                   |
| <b>EBITDA (Operating income before depreciation and amortization)</b> | <b>9 674</b>         | <b>2 098</b>         | <b>-1 533</b>      | <b>-5 452</b>      | <b>-15 637</b>               |
| Depreciation and amortization on intangible assets                    | -10 605              | -8 222               | -5 135             | -4 107             | -17 685                      |
| Depreciation and amortization on tangible assets                      | -5 236               | -6 562               | -2 682             | -3 150             | -12 353                      |
| <b>Operating income</b>   | <b>-6 167</b>        | <b>-12 686</b>       | <b>-9 350</b>      | <b>-12 709</b>     | <b>-45 675</b>               |

1) See note 4 for "Other operating revenues and expenses"

2) After dilution

## Consolidated Statement of Comprehensive Income

| SEK Thousands  | January-June<br>2021 | January-June<br>2020 | April-June<br>2021 | April-June<br>2020 | January-<br>December<br>2020 |
|--|----------------------|----------------------|--------------------|--------------------|------------------------------|
| <b>Net income</b>  | <b>-2 908</b>        | <b>-9 475</b>        | <b>-8 941</b>      | <b>-16 018</b>     | <b>-43 735</b>               |
| <b>Other comprehensive income</b>  |                      |                      |                    |                    |                              |
| Items that may be reclassified to the income statement                       |                      |                      |                    |                    |                              |
| Exchange rate differences  | 3 714                | 423                  | -3 704             | -5 226             | -16 410                      |
| Tax attributable to items that have been or can be transferred to net income | -                    | -146                 | -                  | 319                | -                            |
| <b>Total other comprehensive income</b>                                      | <b>3 714</b>         | <b>277</b>           | <b>-3 704</b>      | <b>-4 907</b>      | <b>-16 410</b>               |
| <b>Total comprehensive income</b>  | <b>806</b>           | <b>-9 198</b>        | <b>-12 645</b>     | <b>-20 925</b>     | <b>-60 145</b>               |
| <b>Attributable to</b>   |                      |                      |                    |                    |                              |
| Parent Company's shareholders  | 806                  | -9 198               | -12 645            | -20 925            | -60 145                      |

## Condensed Consolidated Statement of Financial Position

| SEK Thousands   | 210630           | 200630         | 201231           |
|---|------------------|----------------|------------------|
| <b>ASSETS</b>   |                  |                |                  |
| Goodwill  | 225 468          | 65 788         | 223 938          |
| Capitalized development expenditure                                     | 419 891          | 287 282        | 393 969          |
| Other intangible fixed assets   | 8 020            | 6 115          | 6 750            |
| Fixed assets  | 22 140           | 23 981         | 21 334           |
| Financial assets  | 40 823           | 15 194         | 41 088           |
| <b>Total non-current assets</b>   | <b>716 342</b>   | <b>398 360</b> | <b>687 079</b>   |
| Inventories   | 72 735           | 48 025         | 59 351           |
| Current receivables   | 48 835           | 34 030         | 49 643           |
| Liquid funds  | 311 419          | 139 993        | 354 236          |
| <b>Total current assets</b>   | <b>432 989</b>   | <b>222 048</b> | <b>463 230</b>   |
| <b>Total assets</b>   | <b>1 149 331</b> | <b>620 408</b> | <b>1 150 309</b> |
| <b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>                             |                  |                |                  |
| Shareholders' equity, attributable to the Parent Company's shareholders | 1 010 507        | 569 653        | 1 008 461        |
| Long-term interest-bearing liabilities                                  | 1 646            | 2 585          | 1 474            |
| Long-term non-interest-bearing liabilities                              | 66 877           | 2 889          | 66 314           |
| Short-term interest-bearing liabilities                                 | 4 148            | 6 061          | 5 738            |
| Short-term non-interest-bearing liabilities                             | 66 153           | 39 220         | 68 322           |
| <b>Total shareholders' equity and liabilities</b>                       | <b>1 149 331</b> | <b>620 408</b> | <b>1 150 309</b> |

## Condensed Consolidated Cash Flow Statement

|  | January-June<br>2021 | January-June<br>2020 | April-June<br>2021 | April-June<br>2020 | January-<br>December<br>2020 |
|--|----------------------|----------------------|--------------------|--------------------|------------------------------|
| Income after financial items                 | -2 497               | -12 184              | -10 761            | -18 758            | -57 263                      |
| Adjustment for items not affecting cash flow | 8 958                | 18 660               | 10 117             | 17 287             | 49 355                       |
| Paid taxes                                   | -1 743               | -379                 | -1 471             | 428                | 142                          |
| Change in inventories                        | -9 452               | -4 279               | -7 832             | 894                | -14 155                      |
| Change in trade receivables                  | 4 725                | 23 456               | 2 060              | 9 821              | 20 584                       |
| Change in trade payables                     | -3 033               | -13 659              | -5 479             | -7 286             | -10 929                      |
| <b>Cash flow from operating activities</b>   | <b>-3 042</b>        | <b>11 615</b>        | <b>-13 366</b>     | <b>2 386</b>       | <b>-12 266</b>               |
| Cash flow from investing activities          | -42 338              | -29 746              | -22 833            | -13 894            | -266 532                     |
| Cash flow from financing activities          | -927                 | -1 629               | 132                | -140               | 482 768                      |
| <b>Cash flow for the period</b>              | <b>-46 307</b>       | <b>-19 760</b>       | <b>-36 067</b>     | <b>-11 648</b>     | <b>203 970</b>               |
| Liquid funds at beginning of period          | 354 236              | 159 946              | 350 324            | 158 608            | 159 946                      |
| Exchange rate difference in liquid funds     | 3 490                | -193                 | -2 838             | -6 967             | -9 680                       |
| <b>Liquid funds at end of period</b>         | <b>311 419</b>       | <b>139 993</b>       | <b>311 419</b>     | <b>139 993</b>     | <b>354 236</b>               |

## Consolidated Change in Shareholders Equity

| SEK Thousands  | Attributable to Parent Company's shareholders |                          |               |  | Sum<br>shareholders'<br>equity |
|--|---|--------------------------|---------------|--|--------------------------------|
|  | Share capital                                 | Other paid in<br>capital | Reserves      | Retained<br>earnings incl.<br>profit for the<br>year |                                |
| <b>Shareholders' equity as of January 1, 2020</b>  | <b>680</b>                                    | <b>515 753</b>           | <b>16 228</b> | <b>44 860</b>  | <b>577 521</b>                 |
| Total comprehensive income January - June 2020   | -   | -                        | 277           | -9 476   | -9 199                         |
| Share warrant program  | -   | 1 331                    | -             | -  | 1 331                          |
| <b>Shareholders' equity as of June 30, 2020</b>  | <b>680</b>                                    | <b>517 084</b>           | <b>16 505</b> | <b>35 384</b>  | <b>569 653</b>                 |
| Total comprehensive income July - December 2020  | -   | -                        | -16 688       | -34 258  | -50 946                        |
| Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax | 54  | 489 640                  | -             | -  | 489 694                        |
| Share warrant program  | -   | 60                       | -             | -  | 60                             |
| <b>Shareholders' equity as of December 31, 2020</b>  | <b>734</b>                                    | <b>1 006 784</b>         | <b>-183</b>   | <b>1 126</b>   | <b>1 008 461</b>               |
| Total comprehensive income January - June 2021   | -   | -                        | 3 714         | -2 908   | 806                            |
| Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax | 1   | -                        | -             | -  | 1                              |
| Share warrant program  | -   | 1 239                    | -             | -  | 1 239                          |
| <b>Shareholders' equity as of June 30, 2021</b>  | <b>735</b>                                    | <b>1 008 023</b>         | <b>3 531</b>  | <b>-1 782</b>  | <b>1 010 507</b>               |

## Condensed Consolidated Statement of Net Income per quarter

| SEK Thousands   | Apr-Jun<br>2021 | Jan-Mar<br>2021 | Oct-Dec<br>2020 | Jul-Sep<br>2020 | Apr-Jun<br>2020 | Jan-Mar<br>2020 | Oct-Dec<br>2019 | Jul-Sep<br>2019 |
|---|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Net sales   | 59 263          | 58 325          | 60 277          | 42 736          | 30 393          | 46 455          | 62 416          | 54 334          |
| Cost of goods sold  | -14 716         | -15 645         | -18 920         | -9 602          | -7 291          | -11 073         | -16 710         | -15 791         |
| <b>Gross income</b>   | <b>44 547</b>   | <b>42 680</b>   | <b>41 357</b>   | <b>33 134</b>   | <b>23 102</b>   | <b>35 382</b>   | <b>45 706</b>   | <b>38 543</b>   |
| Selling expenses  | -20 613         | -19 696         | -19 229         | -13 470         | -12 360         | -14 840         | -18 372         | -14 376         |
| Administrative expenses   | -14 605         | -11 033         | -11 163         | -8 462          | -5 069          | -5 648          | -7 152          | -6 029          |
| Research and development costs  | -14 034         | -15 529         | -15 886         | -11 233         | -12 186         | -16 873         | -17 964         | -16 827         |
| Other operating revenues and expenses <sup>1)</sup>                   | -4 645          | 6 761           | -9 406          | -18 631         | -6 196          | 2 002           | -622            | 966             |
| <b>Operating income</b>   | <b>-9 350</b>   | <b>3 183</b>    | <b>-14 328</b>  | <b>-18 661</b>  | <b>-12 709</b>  | <b>23</b>       | <b>1 596</b>    | <b>2 277</b>    |
| Financial income and expenses   | -1 411          | 5 081           | -11 610         | -481            | -6 047          | 6 550           | -3 838          | 3 210           |
| <b>Income after financial items</b>                                   | <b>-10 761</b>  | <b>8 264</b>    | <b>-25 938</b>  | <b>-19 142</b>  | <b>-18 756</b>  | <b>6 573</b>    | <b>-2 242</b>   | <b>5 487</b>    |
| Taxes   | 1 820           | -2 231          | 6 363           | 4 457           | 2 738           | -30             | 340             | -558            |
| <b>Net income</b>   | <b>-8 941</b>   | <b>6 033</b>    | <b>-19 575</b>  | <b>-14 685</b>  | <b>-16 018</b>  | <b>6 543</b>    | <b>-1 902</b>   | <b>4 929</b>    |
| <b>Attributable to</b>  |                 |                 |                 |                 |                 |                 |                 |                 |
| Parent Company's shareholders   | -8 941          | 6 033           | -19 575         | -14 685         | -16 018         | 6 543           | -1 902          | 4 929           |
| Earnings per share, SEK   | -0,31           | 0,21            | -0,68           | -0,51           | -0,60           | 0,25            | -0,07           | 0,19            |
| Earnings per share, SEK <sup>2)</sup>                                 | -0,31           | 0,20            | -0,67           | -0,51           | -0,60           | 0,25            | -0,07           | 0,18            |
| Average number of outstanding shares                                  | 28 727 266      | 28 719 136      | 28 719 136      | 28 601 434      | 26 600 496      | 26 600 496      | 26 600 496      | 26 600 496      |
| Average number of outstanding shares <sup>2)</sup>                    | 29 101 266      | 29 444 136      | 29 327 136      | 28 975 434      | 26 600 496      | 26 600 496      | 26 879 496      | 26 879 496      |
| Number of shares at closing day                                       | 28 752 397      | 28 719 136      | 28 719 136      | 28 719 136      | 26 600 496      | 26 600 496      | 26 600 496      | 26 600 496      |
| Number of shares at closing day <sup>2)</sup>                         | 29 126 397      | 29 444 136      | 29 444 136      | 29 093 136      | 26 600 496      | 26 600 496      | 26 879 496      | 26 879 496      |
| <b>EBITDA (Operating income before depreciation and amortization)</b> | <b>-1 533</b>   | <b>11 207</b>   | <b>-6 506</b>   | <b>-11 229</b>  | <b>-5 452</b>   | <b>7 550</b>    | <b>8 479</b>    | <b>9 025</b>    |
| Depreciation and amortization on intangible assets                    | -5 135          | -5 470          | -5 349          | -4 114          | -4 107          | -4 115          | -4 107          | -4 099          |
| Depreciation and amortization on tangible assets                      | -2 682          | -2 554          | -2 473          | -3 318          | -3 150          | -3 412          | -2 776          | -2 649          |
| <b>Operating income</b>   | <b>-9 350</b>   | <b>3 183</b>    | <b>-14 328</b>  | <b>-18 661</b>  | <b>-12 709</b>  | <b>23</b>       | <b>1 596</b>    | <b>2 277</b>    |

<sup>1)</sup> See note 3 for "Other operating revenues and expenses"

<sup>2)</sup> After dilution

## Consolidated Statement of Comprehensive Income per quarter

| SEK Thousands   | Apr - Jun<br>2021 | Jan-Mar<br>2021 | Oct-Dec<br>2020 | Jul-Sep<br>2020 | Apr-Jun<br>2020 | Jan-Mar<br>2020 | Oct-Dec<br>2019 | Jul-Sep<br>2019 |
|---|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| <b>Net income</b>   | <b>-8 941</b>     | <b>6 033</b>    | <b>-19 575</b>  | <b>-14 685</b>  | <b>-16 018</b>  | <b>6 543</b>    | <b>-1 902</b>   | <b>4 929</b>    |
| <b>Other comprehensive income</b>   |                   |                 |                 |                 |                 |                 |                 |                 |
| Items that may be reclassified to the income statement:                                   |                   |                 |                 |                 |                 |                 |                 |                 |
| Exchange rate differences   | -3 704            | 7 418           | -13 179         | -3 654          | -5 226          | 5 649           | -3 691          | 4 531           |
| Tax attributable to items that have been transferred, or can be transferred to net income | -                 | -               | -153            | 299             | 319             | -465            | 343             | -487            |
| <b>Total other comprehensive income</b>   | <b>-3 704</b>     | <b>7 418</b>    | <b>-13 332</b>  | <b>-3 355</b>   | <b>-4 907</b>   | <b>5 184</b>    | <b>-3 348</b>   | <b>4 044</b>    |
| <b>Total comprehensive income</b>   | <b>-12 645</b>    | <b>13 451</b>   | <b>-32 907</b>  | <b>-18 040</b>  | <b>-20 925</b>  | <b>11 727</b>   | <b>-5 250</b>   | <b>8 973</b>    |
| <b>Attributable to</b>  |                   |                 |                 |                 |                 |                 |                 |                 |
| Parent Company's shareholders   | -12 645           | 13 451          | -32 907         | -18 040         | -20 925         | 11 727          | -5 250          | 8 973           |

## Consolidated key ratios

| SEK Thousands                       | January-June<br>2021 | January-June<br>2020 | April-June<br>2021 | April-June<br>2020 | January-<br>December<br>2020 |
|-------------------------------------|----------------------|----------------------|--------------------|--------------------|------------------------------|
| Gross margin non-Durable goods, %   | 76                   | 80                   | 76                 | 81                 | 77                           |
| Gross margin, %                     | 74                   | 76                   | 75                 | 76                 | 74                           |
| EBITDA, %                           | 8                    | 3                    | -3                 | -18                | -9                           |
| EBITDA (adjusted), %                | 12                   | 5                    | 14                 | -3                 | 11                           |
| Operating margin, %                 | -5                   | -17                  | -16                | -42                | -25                          |
| Net margin, %                       | -5                   | -12                  | -16                | -53                | -24                          |
| Equity/assets ratio, %              | 88                   | 92                   | 88                 | 92                 | 88                           |
| Income per share, SEK               | -0,10                | -0,36                | -0,31              | -0,60              | -1,61                        |
| Shareholders' equity per share, SEK | 35,15                | 21,42                | 35,15              | 21,42              | 35,11                        |
| Share price on closing day, SEK     | 350                  | 180                  | 350                | 180                | 314                          |
| Market cap on closing day, MSEK     | 10 063               | 4 788                | 10 063             | 4 788              | 9 018                        |

## Condensed Income Statement, Parent Company

| SEK Thousands                         | January-June<br>2021 | January-June<br>2020 | April-June<br>2021 | April-June<br>2020 | January-<br>December<br>2020 |
|---------------------------------------|----------------------|----------------------|--------------------|--------------------|------------------------------|
| Net sales                             | 95 995               | 58 547               | 57 053             | 25 373             | 134 122                      |
| Cost of goods sold                    | -18 252              | -13 757              | -13 928            | -4 651             | -36 107                      |
| <b>Gross income</b>                   | <b>77 743</b>        | <b>44 790</b>        | <b>43 125</b>      | <b>20 722</b>      | <b>98 015</b>                |
| Selling expenses                      | -21 200              | -16 421              | -11 254            | -7 788             | -36 675                      |
| Administrative expenses               | -26 300              | -9 681               | -18 038            | -4 664             | -27 602                      |
| Research and development expenses     | -23 948              | -31 353              | -10 835            | -17 145            | -65 268                      |
| Other operating revenues and expenses | -331                 | -5 858               | 137                | -5 896             | -10 074                      |
| <b>Operating income</b>               | <b>5 964</b>         | <b>-18 523</b>       | <b>3 135</b>       | <b>-14 771</b>     | <b>-41 604</b>               |
| Financial income and expenses         | 4 353                | 1 594                | -1 022             | -7 333             | -10 609                      |
| <b>Income after financial items</b>   | <b>10 317</b>        | <b>-16 929</b>       | <b>2 113</b>       | <b>-22 104</b>     | <b>-52 213</b>               |
| Year end dispositions                 | -                    | -                    | -                  | -                  | 4 200                        |
| Taxes                                 | -3 063               | 3 409                | -517               | 3 409              | 9 577                        |
| <b>Net income</b>                     | <b>7 254</b>         | <b>-13 520</b>       | <b>1 596</b>       | <b>-18 695</b>     | <b>-38 436</b>               |

The parent company has no items to be recognized in other comprehensive income and therefore no statement of comprehensive income has been presented. Depreciation in the period amounted to SEK 9,763 thousand (9,915), of which SEK 4,895 thousand (4,413) in the quarter.

## Condensed Balance Sheet, Parent Company

| SEK Thousands                                     | 210630           | 200630         | 201231           |
|---|------------------|----------------|------------------|
| <b>ASSETS</b>                                     |                  |                |                  |
| Intangible fixed assets                           | 268 862          | 224 707        | 245 777          |
| Property, plant and equipment                     | 6 219            | 6 756          | 5 902            |
| Financial assets                                  | 488 806          | 186 921        | 453 598          |
| <b>Total non-current assets</b>                   | <b>763 887</b>   | <b>418 384</b> | <b>705 277</b>   |
| Inventories                                       | 18 210           | 21 602         | 16 561           |
| Current receivables                               | 18 775           | 21 833         | 25 602           |
| Cash and bank                                     | 284 798          | 116 814        | 333 318          |
| <b>Total current assets</b>                       | <b>321 783</b>   | <b>160 249</b> | <b>375 481</b>   |
| <b>Total assets</b>                               | <b>1 085 670</b> | <b>578 633</b> | <b>1 080 758</b> |
| <b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>       |                  |                |                  |
| Shareholders' equity                              | 1 009 311        | 535 961        | 1 000 817        |
| Untaxed reserves                                  | -                | 4 200          | -                |
| Provisions  | 1 418            | 1 315          | 1 311            |
| Long-term non-interest-bearing liabilities        | 40 500           | -              | 41 392           |
| Short-term non-interest-bearing liabilities       | 34 441           | 37 157         | 37 238           |
| <b>Total shareholders' equity and liabilities</b> | <b>1 085 670</b> | <b>578 633</b> | <b>1 080 758</b> |



# Supplementary notes

Disclosures in accordance with IAS 34.16A are included in the financial statements and notes, as well as elsewhere in the Interim Report.

## Note 1. Accounting principles

For the Group, the report is presented pursuant to the Swedish Annual Accounts Act and IAS 34, Interim Financial Reporting, and for the Parent Company pursuant to the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities. Accounting principles applied to the Group and the parent company correspond, unless otherwise stated below, with the accounting policies used for the preparation of the latest Annual Report.

## Note 2. Financial instruments

The Group's financial assets and liabilities valued at cost amounted to SEK 360 million (174) and SEK 66 million (39) respectively. The book value is considered to be a reasonable approximation of the fair value of these assets and liabilities in the Balance Sheet. Furthermore, the Group recognizes a liability of SEK 40.5 million (-) relating to an additional purchase price linked to acquisitions, at fair value.

## Note 3. Consolidated operating segments

Net sales and costs of goods sold are divided into the segments durable goods and non-durable goods. Durable goods refer to income from the sale and rental of machinery used in organ perfusion. 'Non-durable goods' refers to income from sales of consumables used in preservation and perfusion of organs.

| SEK Thousands           | January-June      |               |               |            |                    |               |
|-------------------------|-------------------|---------------|---------------|------------|--------------------|---------------|
|                         | Non-Durable goods |               | Durable goods |            | Total consolidated |               |
|                         | 2021              | 2020          | 2021          | 2020       | 2021               | 2020          |
| Net sales               | 111 120           | 72 189        | 6 468         | 4 659      | 117 588            | 76 848        |
| Cost of goods sold      | -27 174           | -14 415       | -3 187        | -3 949     | -30 361            | -18 364       |
| <b>Gross income</b>     | <b>83 946</b>     | <b>57 774</b> | <b>3 281</b>  | <b>710</b> | <b>87 227</b>      | <b>58 484</b> |
| <b>Gross margin (%)</b> | <b>76</b>         | <b>80</b>     | <b>51</b>     | <b>15</b>  | <b>74</b>          | <b>76</b>     |

| SEK Thousands           | April-June        |               |               |            |                    |               |
|-------------------------|-------------------|---------------|---------------|------------|--------------------|---------------|
|                         | Non-Durable goods |               | Durable goods |            | Total consolidated |               |
|                         | 2021              | 2020          | 2021          | 2020       | 2021               | 2020          |
| Net sales               | 56 259            | 28 003        | 3 004         | 2 390      | 59 263             | 30 393        |
| Cost of goods sold      | -13 707           | -5 316        | -1 009        | -1 975     | -14 716            | -7 291        |
| <b>Gross income</b>     | <b>42 552</b>     | <b>22 687</b> | <b>1 995</b>  | <b>415</b> | <b>44 547</b>      | <b>23 102</b> |
| <b>Gross margin (%)</b> | <b>76</b>         | <b>81</b>     | <b>66</b>     | <b>17</b>  | <b>75</b>          | <b>76</b>     |

## Note 4. Other operating revenue and expenses

| SEK Thousands   | Apr - Jun<br>2021 | Jan-Mar<br>2021 | Oct-Dec<br>2020 | July-Sep<br>2020 | April-June<br>2020 | Jan-March<br>2020 | Oct-Dec<br>2019 | July-Sep<br>2019 |
|---|-------------------|-----------------|-----------------|------------------|--------------------|-------------------|-----------------|------------------|
| Cost of cash-based incentive program for employees outside Sweden | -3 860            | 7 084           | -8 332          | -12 469          | -                  | 2 541             | 237             | 2 253            |
| Cost of reorganization  | -                 | -               | -               | -5 375           | -4 498             | -                 | -               | -                |
| Other   | -785              | -323            | -1 074          | -786             | -1 698             | -539              | -859            | -1 287           |
| <b>Total</b>  | <b>-4 645</b>     | <b>6 761</b>    | <b>-9 406</b>   | <b>-18 630</b>   | <b>-6 196</b>      | <b>2 002</b>      | <b>-622</b>     | <b>966</b>       |

# Reconciliation of alternative performance measures

This report includes key figures not defined in IFRS, but have been included in the report as management considers that this data enables investors to analyze the Group's performance and financial position. Investors should consider alternative ratios as a complement rather than a substitute for financial information under IFRS.

## EBITDA

| SEK Thousands   | January-<br>June<br>2021 | January-<br>June<br>2020 | April - June<br>2021 | April - June<br>2020 | January-<br>December<br>2020 |
|---|--------------------------|--------------------------|----------------------|----------------------|------------------------------|
| <b>Operating income</b>   | <b>-6 167</b>            | <b>-12 686</b>           | <b>-9 350</b>        | <b>-12 709</b>       | <b>-45 675</b>               |
| Depreciation and amortization on intangible assets                    | 10 605                   | 8 222                    | 5 135                | 4 107                | 17 685                       |
| Depreciation and amortization on tangible assets                      | 5 236                    | 6 562                    | 2 682                | 3 150                | 12 353                       |
| <b>EBITDA (Operating income before depreciation and amortization)</b> | <b>9 674</b>             | <b>2 098</b>             | <b>-1 533</b>        | <b>-5 452</b>        | <b>-15 637</b>               |

## Gross margin

| SEK Thousands             | January-<br>June<br>2021 | January-<br>June<br>2020 | April - June<br>2021 | April - June<br>2020 | January-<br>December<br>2020 |
|---------------------------|--------------------------|--------------------------|----------------------|----------------------|------------------------------|
| Operating income          |                          |                          |                      |                      |                              |
| <i>Net sales</i>          | 117 588                  | 76 848                   | 59 263               | 30 393               | 179 861                      |
| Operating expenses        |                          |                          |                      |                      |                              |
| <i>Cost of goods sold</i> | -30 361                  | -18 364                  | -14 716              | -7 291               | -46 886                      |
| <b>Gross income</b>       | <b>87 227</b>            | <b>58 484</b>            | <b>44 547</b>        | <b>23 102</b>        | <b>132 975</b>               |
| <b>Gross margin %</b>     | <b>74</b>                | <b>76</b>                | <b>75</b>            | <b>76</b>            | <b>74</b>                    |

## Gross margin non-durable goods

| SEK Thousands                            | January-<br>June<br>2021 | January-<br>June<br>2020 | April - June<br>2021 | April - June<br>2020 | January-<br>December<br>2020 |
|--|--------------------------|--------------------------|----------------------|----------------------|------------------------------|
| Operating income                         |                          |                          |                      |                      |                              |
| <i>Net sales of non-Durable goods</i>    | 111 120                  | 72 189                   | 56 259               | 28 003               | 169 425                      |
| Operating expenses                       |                          |                          |                      |                      |                              |
| <i>Cost of non-Durable goods sold</i>    | -27 174                  | -14 415                  | -13 707              | -5 316               | -38 980                      |
| <b>Gross income, non-Durable goods</b>   | <b>83 946</b>            | <b>57 774</b>            | <b>42 552</b>        | <b>22 687</b>        | <b>130 445</b>               |
| <b>Gross margin, non-Durable goods %</b> | <b>76</b>                | <b>80</b>                | <b>76</b>            | <b>81</b>            | <b>77</b>                    |

When calculating gross margin, gross profit is first calculated by subtracting the cost of goods sold from net sales. Gross profit is then set in relation to net sales to obtain the gross margin ratio. Gross margin thus indicates profit after cost of goods sold as a proportion of net sales, and is affected by factors such as pricing, raw materials and manufacturing costs, inventory write-downs and exchange rate effects.

## Equity/assets ratio

| SEK Thousands                | 210630    | 200630    | 201231    |
|------------------------------|-----------|-----------|-----------|
| Shareholders' equity         | 1 010 507 | 569 653   | 1 008 461 |
| Total assets                 | 1 149 331 | 620 408   | 1 150 309 |
| <b>Equity/assets ratio %</b> | <b>88</b> | <b>92</b> | <b>88</b> |

Equity consists of share capital, other contributed capital, reserves, retained earnings including profit for the year in the Group and non-controlling interests. The equity/assets ratio indicates equity as a proportion of total assets and is a measure of the proportion of assets financed by equity.

# KPI definitions

| Key ratio                                     | Definition  | Justification to use of key ratio  |
|---|---|--|
| <b>Gross margin non-durable goods, %</b>      | Gross income segment non-durable goods as a percentage of the net sales of segment non-durable goods.         | The company believes that the key ratio provides an in-depth understanding of the company's profitability for operations for non-durable goods. Since the pricing strategy for durable goods differs from the pricing strategy from all other operations, the gross margin is presented separately from durable goods. |
| <b>Gross margin, %</b>                        | Gross income as a percentage of net sales for the period  | The company believes that the key ratio provides an in-depth understanding of the company's profitability  |
| <b>EBITDA margin, %</b>                       | Operating income before depreciation and amortization as a percentage of net sales for the period             | The company believes that the key ratio provides an in-depth understanding of the company's profitability  |
| <b>Operating margin, %</b>                    | Operating income as a percentage of net sales for the period.   | The company believes that the key ratio provides an in-depth understanding of the company's profitability  |
| <b>Net margin, %</b>                          | Operating income as a percentage of net sales for the period.   | The company believes that the key ratio provides an in-depth understanding of the company's profitability  |
| <b>Equity/assets ratio, %</b>                 | Shareholders' equity and non-controlling interests as a percentage of total assets.                           | The company believes that the equity/asset ratio provides an in-depth understanding of the company's capital structure.  |
| <b>Shareholders' equity per share, SEK</b>    | Shareholders' equity in relation to the number of shares outstanding on the reporting date.                   | The key ratio has been included to give investors an overview of how the company's equity per share has evolved.   |
| <b>Earnings per share, SEK</b>                | Income for the period in relation to the average number of outstanding shares before dilution for the period. | The key ratio has been included to give investors an overview of how the company's earnings per share has evolved.   |
| <b>Earnings per share after dilution, SEK</b> | Income for the period in relation to the average number of outstanding shares after dilution for the period   | The key ratio has been included to give investors an overview of how the company's earnings per share after dilution has evolved.  |

# Glossary

The following explanations are intended to help the reader understand certain specific terms and expressions in XVIVO Perfusion's reports:

|  |   |
|--|---|
| <b>Evaluation</b>                                      | Evaluation of the function of an organ  |
| <b>Ex vivo (Latin for "outside a living organism")</b> | Biological processes in living cells and tissues when they are in an artificial environment outside the body. "Opposite" of in vivo.  |
| <b>EVLP or (Ex Vivo Lung Perfusion)</b>                | Perfusion of a lung outside the body. The procedure is normally done to evaluate a lung before transplantation.   |
| <b>FDA or US Food and Drug Administration</b>          | The FDA is the USA's food and drug authority with responsibility for food, dietary supplements, drugs, cosmetics, medical equipment, radiology equipment, and blood products. FDA approval is required to market a medical device on the US market  |
| <b>HDE or Humanitarian Device Exemption</b>            | A humanitarian device exemption (HDE) application can be submitted to the FDA for a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States per year. An HDE is similar in both form and content to a Premarket Approval (PMA) application but is exempt from the efficacy requirements of a PMA.   |
| <b>Hypothermic non-ischemic perfusion of heart</b>     | Circulation of the cooled, dormant donated heart with supply of oxygen and necessary nutrients during transport to the recipient.   |
| <b>Durable goods</b>                                   | Revenues from the sale or rental of machinery for mechanical perfusion and preservation of organs.  |
| <b>Clinical study/trial</b>                            | A study in healthy or sick people to study the effect of a drug or treatment method.  |
| <b>Machine perfusion</b>                               | New technology that improves preservation and evaluation of organs, which means more organs can be used for transplants. In the Thoracic business area this includes STEEN Solution™, XPS™, LS™, Lung Assist and Heart Assist as well as other products and services related to the use of those products. In the Abdominal business area this includes Kidney Assist Transport, Kidney Assist and Liver Assist as well as other products and services related to the use of those machines |
| <b>OPO or Organ Procurement Organization</b>           | In the United States, an organ procurement organization (OPO) is a non-profit organization responsible for the evaluation and procurement of deceased-donor organs for organ transplantation. There are approximately 58 such organizations in the United States.   |
| <b>Perfusion</b>                                       | Passage of a fluid through an organ's blood vessels.  |
| <b>PMA or Premarket Approval</b>                       | Premarket approval (PMA) is the FDA - process of scientific and regulatory review to evaluate the safety and efficacy of a medical device.  |
| <b>Preclinical study</b>                               | Research performed before a drug or method of treatment is sufficiently documented to be studied in humans.   |
| <b>Preservation</b>                                    | Storage and maintenance of an organ outside the body before transplantation.  |
| <b>Reimbursement</b>                                   | Reimbursement is used in the health insurance system in order for healthcare providers to be reimbursed faster and more easily for accrued expenses from a private or public insurance company (in the United States, e.g. Medicare).   |
| <b>Static preservation</b>                             | Static preservation refers to preservation methods where the organ is cooled during transport and before transplantation. In the Thoracic business area, this includes Perfadex® Plus as well as other products and services related to the use of that product.  |
| <b>Xeno-transplantation</b>                            | Transplantation of living cells, tissues or organs from one species to another.   |
| <b>Other Sales</b>                                     | In terms of product category, Other sales refers to income relating to freight, service and training.   |

# Extending horizons



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