



# Interim report January – March 2021

XVIVO Perfusion AB (publ)

# XVIVO



# Interim report January – March 2021

# Q1 2021

## First quarter 2021 (1 Jan - 31 Mar)

- Net sales amounted to SEK 58.3 million (46.5), corresponding to an increase of 26 percent in SEK and 38 percent in local currencies. Net sales of non-durable goods amounted to SEK 54.9 million (44.2), corresponding to an increase of 24 percent in SEK and 36 percent in local currencies.
- Machine perfusion constituted 53 percent (31) of net sales.
- Adjusted operating profit before depreciation and amortization (EBITDA) amounted to SEK 6.3 million (5.1), corresponding to an adjusted EBITDA margin of 11 percent (11). Reported EBITDA amounted to SEK 11.2 million (7.6), corresponding to an EBITDA margin of 19 percent (16).
- Adjusted operating profit (EBIT) amounted to SEK -1.8 million (-2.5). Reported EBIT amounted to SEK 3.2 million (0.0).
- Net profit amounted to SEK 6.0 million (6.5). Earnings per share amounted to SEK 0.21 (0.25).
- Cash and cash equivalents at the end of the quarter amounted to SEK 350.3 million (158.7).

## Significant events during the quarter

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

## Key ratios

| TSEK                                    | January-March<br>2021 | January-March<br>2020 | Full year<br>2020 |
|---|-----------------------|-----------------------|-------------------|
| Net sales                               | 58,325                | 46,455                | 179,861           |
| Non-Durable goods                       | 54,861                | 44,186                | 169,425           |
| Durable goods                           | 3,464                 | 2,269                 | 10,436            |
| Machine perfusion share of net sales, % | 53                    | 31                    | 43                |
| Gross margin, %                         | 73                    | 76                    | 74                |
| Non-Durable goods                       | 75                    | 79                    | 77                |
| Durable goods                           | 37                    | 13                    | 24                |
| EBITDA                                  | 11,207                | 7,550                 | -15,637           |
| EBITDA (adjusted) <sup>1)</sup>         | 6,268                 | 5,009                 | 20,172            |
| Earnings per share, SEK                 | 0.21                  | 0.25                  | -1.61             |
| Cash flow from operating activities     | 10,324                | 9,229                 | -12,266           |

<sup>1)</sup> Adjusted for positive effect from decrease of cost provision attributable to cash-based incentive program for employees outside of Sweden, SEK 7.1 million, and integration costs amounting SEK -2.2 million. Net adjustment totals SEK 4.9 (2.5) million for the quarter.

# Many highlights in the first quarter

The first quarter of the year was positive in several respects. Sales of machine perfusion in Thoracic totaled SEK 21 million, an increase of 45 percent year-on-year. In the US, the AOPO (the Association of Organ Procurement Organizations) presented a new groundbreaking target of increasing the number of transplants by 50 percent in the period until 2026, which creates important business opportunities for XVIVO. The main highlight in the first quarter was an article in the New England Journal of Medicine in February which emphasized the significant advantages of oxygenated perfusion of liver before transplantation.



Dag Andersson, CEO

Sales totaled SEK 58 million (46), corresponding to an increase of 38 percent in local currency. The Covid-19 pandemic has continued to have an effect on global healthcare. During the first quarter, we could see some recovery in the number of transplants, primarily on the American market.

Thoracic presented a strong first quarter for machine perfusion, driven by positive progress in North America, which was pleasing. In Abdominal, preparations have started ahead of the coming launch of Kidney Assist Transport in Europe and the US. We expect to submit an application to the US Food and Drug Administration, FDA, shortly. Following approval by the FDA, our commercial organization will be ready to roll out this important product to customers. Price increases have been undertaken according to plan within both Thoracic and Abdominal.

In the US, our most important market, the AOPO (the Association of Organ Procurement Organizations) presented a new target on 18 February. The goal is to increase the number of transplantations in the US by 50 percent in the period until 2026, from today's levels to 50,000 transplantations annually. The goal will be achieved through an increased rate of utilization of donated organs and a sharper focus on innovation. For XVIVO, this is likely to imply significant growth opportunities.

In January, respected scientific publication the New England Journal of Medicine published an article that demonstrated that oxygenated machine perfusion of donated liver has a significant positive effect on post-transplant results. The machine used in the study is CE-marked by XVIVO and is uniquely positioned as the only machine on the market for double oxygenated cold perfusion of liver. This is a major success for XVIVO and an important step in our strategy of becoming the world leader in transplantation in all major organ areas. Our goal is to apply for regulatory approval by the FDA before the end of the year.

We are seeing an increased rate of inclusion in the European heart preservation study. University Hospital AKH in Vienna, one of Europe's largest transplantation centers, has been recruited as the ninth participating center. In the Australian investigator-driven heart preservation study, the first patients received transplants in the quarter. This study is based on a critical question, namely whether XVIVO's heart preservation method can double the maximum period a heart can be transported between donor and recipient with maintained safety. To conclude, Rigshospitalet in Copenhagen will be added to the hospitals included in the PrimECC study. Interest in this study remains significant and it is pleasing that Scandinavia's largest center for heart surgery is now participating.

From April, XVIVO is rolling out a new brand identity that clarifies who we are, what we do and where we are heading. Our vision that no one should need to die while waiting for a new organ has been complemented with a purpose: "Extending Horizons in Organ Transplantation". We are updating our logo and the new design communicates precision, forward motion and technology, but is still warm and human.

Dag Andersson, CEO

"The number of transplants in the US shall increase by 50 percent in the period until 2026"

# 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.

## Vision

Nobody should die waiting for a new organ.

## Purpose

We believe in an extended life of organs.

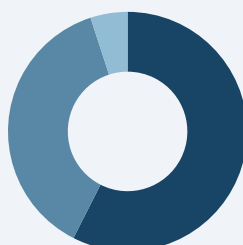
## Target

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

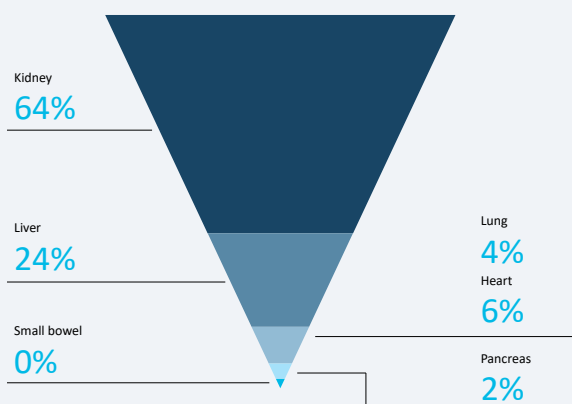


### NET SALES PER REGION (Q1)

■ Americas (57%)  
■ EMEA (38%)  
■ APAC (5%)

# ~98%

of the market addressed with the XVIVO offering



## Strategic areas

### THE WORLD LEADER IN ALL MAJOR ORGANS

XVIVO will build on its strong 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 EXCELLENCE

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-March<br>2021 | January-March<br>2020 | January-December<br>2020 |
|---|-----------------------|-----------------------|--------------------------|
| Net Sales non-Durable Goods   | 54,861                | 44,186                | 169,425                  |
| Net Sales Durable Goods   | 3,464                 | 2,269                 | 10,436                   |
| <b>Net Sales Total</b>  | <b>58,325</b>         | <b>46,455</b>         | <b>179,861</b>           |
| Cost of Goods non-Durable Goods                                       | -13,467               | -9,099                | -38,980                  |
| Cost of Goods Durable goods   | -2,178                | -1,974                | -7,906                   |
| Cost of Goods Total   | -15,645               | -11,073               | -46,886                  |
| Gross income non-Durable Goods  | 41,394                | 35,087                | 130,445                  |
| Gross margin non-Durable Goods, %                                     | 75%                   | 79%                   | 77%                      |
| Gross income Durable Goods  | 1,286                 | 295                   | 2,530                    |
| Gross margin Durable Goods, %   | 37%                   | 13%                   | 24%                      |
| Gross income Total  | 42,680                | 35,382                | 132,975                  |
| Gross margin Total, %   | 73%                   | 76%                   | 74%                      |
| Selling expenses  | -19,696               | -14,840               | -59,899                  |
| Administrative expenses   | -11,033               | -5,648                | -30,342                  |
| Research and development expenses                                     | -15,529               | -16,873               | -56,178                  |
| Other operating revenues and expenses <sup>1)</sup>                   | 6,761                 | 2,002                 | -32,231                  |
| <b>Operating Income</b>   | <b>3,183</b>          | <b>23</b>             | <b>-45,675</b>           |
| Amortization and depreciation cost of goods sold                      | -79                   | -215                  | -462                     |
| Depreciation administrative expenses                                  | -1,380                | -763                  | -3,154                   |
| Amortization of research and development expenses                     | -5,934                | -5,032                | -21,133                  |
| Depreciation other operative expenses                                 | -631                  | -1,517                | -5,289                   |
| <b>EBITDA (Operating income before depreciation and amortization)</b> | <b>11,207</b>         | <b>7,550</b>          | <b>-15,637</b>           |
| EBITDA, %   | 19%                   | 16%                   | -9%                      |
| <b>EBITDA (adjusted) <sup>2)</sup></b>                                | <b>6,268</b>          | <b>5,009</b>          | <b>20,172</b>            |
| EBITDA (adjusted), %  | 11%                   | 11%                   | 11%                      |

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

<sup>2)</sup> Adjusted for positive effect from decrease of cost provision attributable to cash-based incentive program for employees outside of Sweden, SEK 7,1 million, and integration costs amounting SEK -2,2 million. Net adjustment totals SEK 4,9 (2,5) million for the quarter.



# Overview

## January – March 2021

### Net sales and income

Net sales increased by 26 percent during the second quarter and amounted to SEK 58.3 million (45.5). That corresponds to an increase of 38 percent in local currencies. Net sales of non-durable goods increased by 24 percent and amounted to SEK 54.9 million (44.2). The increase corresponds to 36 percent in local currency.

We can conclude that the Covid-19 pandemic continued to affect the number of transplantations globally in the first quarter of 2021. Available hospital resources have largely focused on caring for Covid-19 patients and thereby the number of transplanted organs have decreased and waiting lists grown.

Organic sales growth amounted to 10 percent in local currencies. Acquired growth amounted to 28 percent in local currencies.

Machine perfusion constituted 53 percent (31) 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 73 percent (76) and gross margin of non-durable goods amounted to 75 percent (79). The decrease is explained partly by the fact that the comparison quarter does not include the Abdominal business area, which margins are lower than Thoracic, and partly by a changed product mix as sales of static preservation was lower than for the comparison quarter.

Operating profit before depreciation and amortization (EBITDA) profit was positively affected by the dissolution of a cost provision for cash-based incentive programs for employees outside Sweden by SEK 7.1 million and was charged with integration costs by SEK 2.2 million. Adjusted for these items with a net of SEK 4.9 million (2.5), adjusted EBITDA amounts to SEK 6.3 million (5.1), corresponding to an EBITDA margin of 11 percent (11). Reported EBITDA amounted to SEK 11.2 million (7.6), corresponding to an EBITDA margin of 19 percent (16).

Operating income (EBIT) adjusted for the above-mentioned items amounted to SEK -1,8 million (2.5). Reported EBIT amounted to SEK 3.2 million (0.0).

Selling expenses in relation to sales amounted to 34 percent (32) for the quarter. R&D expenses amounted to 27 percent (36) of sales. Administrative expenses amounted to 19 percent (12) of sales.

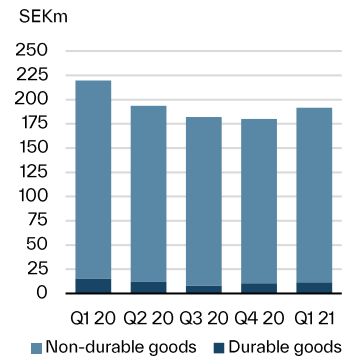
The quarter was charged with costs for the integration of Organ Assist. The acquisition was consolidated into XVIVO on October 1, 2020 and since then, the focus has primarily been on integrating the sales and administration functions. During the first quarter, integration costs affected sale expenses by SEK 1.0 million (-) and administration expenses by SEK 1.1 million (-). During the second quarter, work on centralizing distribution of goods to XVIVO's office in the Netherlands will be intensified. The work is expected to be completed at the beginning of the third quarter and as of that, the integration costs from this acquisition are expected to cease.

Other operating income and operating expenses amounted to SEK 6.8 million (2.0) during the quarter. The item primarily consists of positive effect from the cash-based incentive program for employees abroad of SEK 7.1 million. The remainder primarily consists of currency conversion effects and depreciation. See Note 4 for more information.

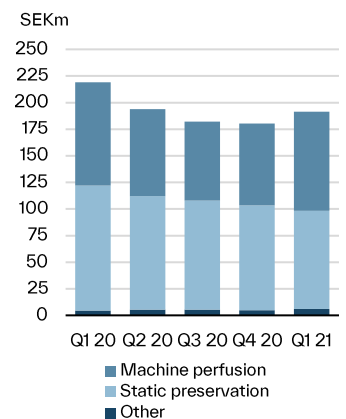
Net financial income and expenses for the quarter amounted to SEK 5.1 million (6.6). The positive contribution is mainly due to positive effects in currency conversion of the Group's cash and cash equivalents.

During the quarter, SEK 16.0 million (15.3) of development expenses 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 expenditures amounted to SEK 5.2 million (3.9) during the quarter, of which SEK 3.9 million (3.9) is attribution of regulatory approvals for the company's products within lung transplantation. The remainder relates to depreciation of R&D projects within the abdominal business.

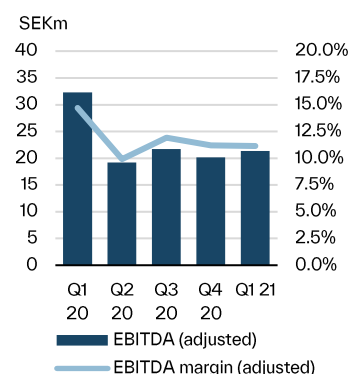
### Net sales per segment (R12)



### Net sales per product category (R12)



### EBITDA och EBITDA-margin (adjusted, R12)



## Cashflow

Cash flow from operating activities during the quarter amounted to SEK 10.3 million (9.2), primarily as a result of the positive operating income during the quarter. Cash flow from investing activities amounted to SEK -19.5 million (-15.9), of which SEK -16.7 million (-15.3) was invested in intangible assets and SEK -2.7 million (-0.5) was invested in tangible assets. Cash flow from financing activities amounted to net SEK -1.0 million (-1.5). Exchange rate translation in the quarter had a positive effect on the cash flow by SEK 6.3 million (6.8). Cash and cash equivalents at the end of the quarter amounted to SEK 350.3 million (158.7).

## 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 87 percent (91) at the end of the period. The company's total credit facility consist of an overdraft facility which at the end of the period amounted to SEK 30 million (30), of which SEK 0.0 million (0.0) was used.

## Significant events during the quarter

### Publication in The New England Journal of Medicine shows complications after liver transplantation significantly reduced with cold, oxygenated machine perfusion

An article published in the scientific journal The New England Journal of Medicine, shows that oxygenated perfusion of the donated liver before transplantation has a significant positive impact on the outcomes after transplantation. The article presents the results from a study performed by a large international consortium of liver transplant centers, lead 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 to 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 the patients that received a machine perfused liver developed biliary complications, compared to 18 percent in the static cold storage group. Furthermore, recipients of a machine perfused liver were less likely to develop compromised hemodynamics after graft reperfusion (so called post-reperfusion syndrome) and had the incidence of early graft dysfunction reduced by nearly half.

The risk of complications for patients that are 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 centres 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 in countries such as the Netherlands, Belgium and the UK. The machine perfusion technology used in the trial prevents complications after transplant and has the potential to increase the number of transplanted patients.

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

### First patients transplanted in the Australian heart preservation study

In the approximately 7,500 heart transplants performed in the world each year the absence of blood flow and oxygen during donor heart transport may translate into poor patient outcome after transplantation. The time that the donated heart may be stored on ice outside of 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 trial including Australian and New Zealand transplant centers will investigate if the novel preservation technology may safely double the transport time for donor heart beyond the current limit of 4 hours.

XVIVO's novel preservation method includes a machine that supplies the 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 this heart preservation technology developed by Professor Stig Steen is a safe method for preservation of human hearts.

# Business area development

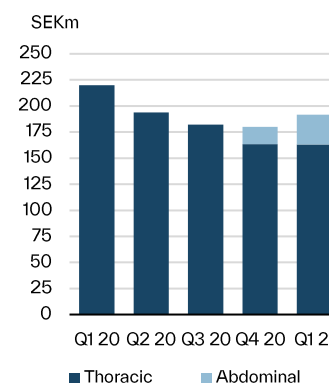
## Thoracic

Business area Thoracic consists of XVIVO's lung and heart transplantation business. Within 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. Within heart transplantation, XVIVO's products are in a clinical study phase. Some pre-clinical sales take place in heart transplantation – mainly within xeno-transplantation.

### Overview

| SEK Thousands     | January-March<br>2021 | January-March<br>2020 |
|-------------------|-----------------------|-----------------------|
| Net sales         | 46,418                | 46,455                |
| Non-Durable goods | 43,763                | 44,186                |
| Durable goods     | 2,655                 | 2,269                 |
| Gross margin, %   | 79                    | 76                    |
| Non-Durable goods | 82                    | 79                    |
| Durable goods     | 31                    | 13                    |

Net sales per business area (R12)



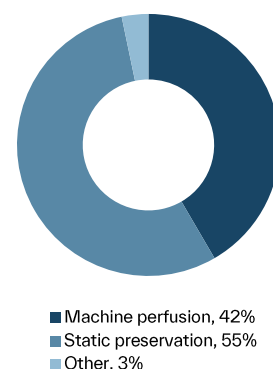
### January – March 2021

Net sales during the quarter were in line with the previous year and amounted to SEK 46.4 million (46.5). In local currencies, this represented growth of 10%. Net sales of non-durable goods decreased by 1 percent to SEK 43.8 million (44.2). In local currencies, however, this represented growth of 9%. During the quarter, one XPS machine was sold to a clinic in Louisville, US.

Machine perfusion accounted for 42 percent (31) of net sales. The increase was primarily driven by a recovery at the established EVLP-clinics in the US. Static preservation and other sales accounted for the remainder of net sales.

Gross margin for the quarter was 79 percent (76). Gross margin of non-durable goods was 82 percent (79). The increases are primarily explained by implemented price increases on the US market in the fourth quarter of 2020 and the European market in the first quarter of 2021.

Net sales per product category, Thoracic (Q1)



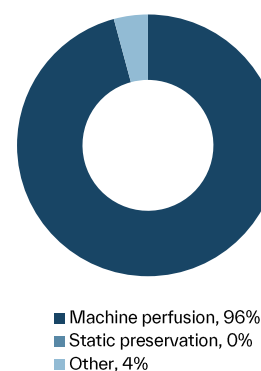
## Abdominal

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

### Overview

| SEK Thousands     | January-March<br>2021 | January-March<br>2020 |
|-------------------|-----------------------|-----------------------|
| Net sales         | 11,907                | -                     |
| Non-Durable goods | 11,098                | -                     |
| Durable goods     | 809                   | -                     |
| Gross margin, %   | 52                    | -                     |
| Non-Durable goods | 51                    | -                     |
| Durable goods     | 59                    | -                     |

Net sales per product category, Abdominal (Q1)



### January – March 2021





Net sales during the quarter amounted to SEK 11.9 million (-). Net sales of non-durable goods amounted to SEK 11.1 million (-). Since XVIVO's abdominal operations were acquired in the fourth quarter of 2020, there are no comparative figures for the Group for the first quarter of 2021. The underlying business showed organic growth of 35 percent. Machine perfusion constituted 96 percent (-) of net sales.

Gross margin of non-durable goods was 51 percent (-). Price increases were implemented according to plan during the first quarter, but the positive effect on the gross profit margin is 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>What primarily limits how many people can receive a heart transplant today is the number available, and with today's technology, usable donated organs, in combination with the time that a donated heart can be outside the body. In collaboration with Professor Stig Steen, XVIVO has developed a holistic solution consisting of fluids and machinery that better preserve the function of the donated heart during transport and thus can contribute to improved results after heart transplantation.</p> | <p>XVIVO is developing a program of clinical multicentre studies. These will form the basis for the application for regulatory approval for the products in all major markets in the world. In Europe, four clinics are now actively including patients at a rate that increased during the quarter. Patients are selected by lottery to be transplanted either with donated hearts transported by XVIVO's method or preserved by conventional ice-box method. A similar multicentre study is also in the planning phase in the US, where the company has received a breakthrough device designation from FDA. In addition to the studies conducted by XVIVO, another Swedish research-initiated study is also conducted using XVIVO's technology. A research-initiated study in Australia transplanted its first patients during the first quarter.</p> |
| <b>Kidney transplantation</b><br> | <p>Similarly to other organs, there is a shortage of transplantable kidneys. Studies have demonstrated that transport of kidneys with ongoing perfusion in many cases improves post-transplant outcomes. The optimal method for transporting donated kidneys is being studied in several ongoing international studies.</p>   | <p>An international study of high quality was published in The Lancet in the fourth quarter of 2020. The study demonstrates significant benefits for the recipient when the kidney is transported perfused with an oxygenated solution. This technology is unique for XVIVO and the company intends to apply for regulatory approval in the US during the second quarter of 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>Similarly to other organs, there is a shortage of transplantable livers. By preserving and evaluating the function of donated liver in an optimized way, potentially more organs with good function could be transplanted. Studies have shown that oxygenated perfusion of the liver before transplantation in some cases reduces the risk of serious complications.</p>   | <p>Study results published in The New England Journal of Medicine in the first quarter of 2021 demonstrate significant benefits of oxygenated machine perfusion of the liver prior to transplantation in post-cardiac donation (DCD). XVIVO's technology was used in the study and XVIVO is the only actor on the market that offers this unique technology. Work to apply for regulatory approval in the US for the company's products will be intensified during the year. The combination of new perfusion technology and solutions will be the focus of future research in the field.</p>  |
| <b>PrimECC®</b><br>              | <p>PrimECC® is a fluid developed in collaboration with Professor Stig Steen and is intended for use in a so-called heart-lung machine. Before connecting the cardiopulmonary machine to a patient, the machine must be filled with fluid, today usually simple saline solutions. In 2016 and 2017, a randomized clinical trial was conducted on 80 patients indicating reduced side effects related to the use of cardiac lung machine when using PrimECC®.</p>   | <p>XVIVO has patents for PrimECC® in the key markets USA, EU, China, and Japan. Several hundred thousand heart surgeries are performed annually, which means great sales potential if good clinical results can be demonstrated. The company is awaiting product launch until the results of the current expanded study in Sweden has been analysed. During the first quarter of 2021, patients continued to be included at Sahlgrenska University Hospital, and Rigshospitalet in Copenhagen was recruited as additional study center.</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 in the research stage for several organs.</p> | <p>XVIVO's technology for preserving heart function is currently used continuously by two world-leading research groups and has been crucial for successful results 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 is 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.xvivoperfusion.com](http://www.xvivoperfusion.com).

## Organization and staff

XVIVO employs 88 people, whereof 37 women and 51 men. Of these, 39 people are employed in Sweden and 49 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

During the period, no transaction with related parties has been carried out.

## 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 development 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 currency 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.xvivoperfusion.com](http://www.xvivoperfusion.com).

## Annual general meeting

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on April 22, 2021 at 15:00. in Gothenburg. XVIVO cares about the health and well-being of its shareholders and employees. It is important for the Company to take social responsibility and help limit the risk of spreading Covid-19. As a precautionary measure, XVIVO intends to keep the Annual General Meeting short and effective. A speech by the CEO will be posted on the Company's website after the end of the meeting. Furthermore, the issues at the meeting will be concentrated on the decision items on the agenda. Shareholders should carefully consider using the possibility of advance voting and the possibility to participate by proxy.

The following have been appointed to be part of XVIVO's Nomination Committee for the 2021 Annual General Meeting:

Henrik Blomquist, appointed by Bure Equity AB  
Martin Lewin, appointed by Eccenovo AB  
Caroline Sjösten, appointed by Swedbank Robur Fonder AB  
Gösta Johannesson, Chairman of the Board

The above have been appointed in accordance with the principles adopted at the 2018 Annual General Meeting on April 27<sup>th</sup> 2018. The Nomination Committee represents 30 percent of the total number of votes as per August 31<sup>st</sup> 2020.

## Outlook

XVIVO can conclude that the Covid-19 pandemic continued to affect the number of transplantations globally in the first quarter of 2021. Available hospital resources have largely focused on caring for Covid-19 patients and thereby the number of transplanted organs have decreased and waiting lists grown. The impact on sales and studies for the remainder of 2021 will depend on to what extent the pandemic affects intensive care on the main markets in the US and Europe. 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 the 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. In the second quarter, the Company intends to submit a 510k application to the FDA for regulatory approval in the US for Kidney Assist Transport. For Liver Assist, the aim is to file an application for deNovo approval to 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 in Sweden is expected to accelerate in line with pressure on intensive care easing.

## Significant events after the reporting period

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

Gothenburg

April 21, 2021

Dag Andersson  
CEO

This report has not been reviewed 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. The information was submitted for publication, through the agency of the contact person set out above on April 21, 2021 at 7.30 am.



### Financial calendar

- Interim Report January-June 2021: Tuesday, July 13, 2021
- Interim Report January-September 2021: Thursday October 28, 2021
- Report on Operations 2021: Thursday, January 27, 2022



### Conference call

CEO and CFO will present the report in a conference call at 2.00 p.m. CET on Wednesday, April 21, 2021.  
Telephone USA: +1 631 913 1422  
Telephone UK: +44 333 300 0804  
PIN: 16950415#



### Contact

Dag Andersson, CEO  
tel: +46 31-788 21 50  
email: dag.andersson@xvivoperfusion.com

Kristoffer Nordström, CFO  
tel: +46 735 19 21 64  
email: kristoffer.nordstrom@xvivoperfusion.com

# Financial statements

## Condensed consolidated statement of net income

| SEK Thousands   | January-March<br>2021 | January-March<br>2020 | January-December<br>2020 |
|---|-----------------------|-----------------------|--------------------------|
| Net sales   | 58,325                | 46,455                | 179,861                  |
| Cost of goods sold  | -15,645               | -11,073               | -46,886                  |
| <b>Gross income</b>   | <b>42,680</b>         | <b>35,382</b>         | <b>132,975</b>           |
| Selling expenses  | -19,696               | -14,840               | -59,899                  |
| Administrative expenses   | -11,033               | -5,648                | -30,342                  |
| Research and development expenses                                     | -15,529               | -16,873               | -56,178                  |
| Other operating revenues and expenses <sup>1)</sup>                   | 6,761                 | 2,002                 | -32,231                  |
| <b>Operating income</b>   | <b>3,183</b>          | <b>23</b>             | <b>-45,675</b>           |
| Financial income and expenses   | 5,081                 | 6,550                 | -11,588                  |
| <b>Income after financial items</b>                                   | <b>8,264</b>          | <b>6,573</b>          | <b>-57,263</b>           |
| Taxes   | -2,231                | -30                   | 13,528                   |
| <b>Net income</b>   | <b>6,033</b>          | <b>6,543</b>          | <b>-43,735</b>           |
| <b>Attributable to</b>  |                       |                       |                          |
| Parent Company's shareholders   | 6,033                 | 6,543                 | -43,735                  |
| Earnings per share, SEK   | 0.21                  | 0.25                  | -1.61                    |
| Earnings per share, SEK <sup>2)</sup>                                 | 0.20                  | 0.25                  | -1.60                    |
| Average number of outstanding shares                                  | 28,719,136            | 26,600,496            | 27,171,352               |
| Average number of outstanding shares <sup>2)</sup>                    | 29,444,136            | 26,600,496            | 27,354,518               |
| Number of shares at closing day                                       | 28,719,136            | 26,600,496            | 28,719,136               |
| Number of shares at closing day <sup>2)</sup>                         | 29,444,136            | 26,600,496            | 29,444,136               |
| <b>EBITDA (Operating income before depreciation and amortization)</b> | <b>11,207</b>         | <b>7,550</b>          | <b>-15,637</b>           |
| Depreciation and amortization on intangible assets                    | -5,470                | -4,115                | -17,685                  |
| Depreciation and amortization on tangible assets                      | -2,554                | -3,412                | -12,353                  |
| <b>Operating income</b>   | <b>3,183</b>          | <b>23</b>             | <b>-45,675</b>           |

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

2) After dilution

## Consolidated statement of total comprehensive income

| SEK Thousands  | January-March<br>2021 | January-March<br>2020 | January-December<br>2020 |
|--|-----------------------|-----------------------|--------------------------|
| <b>Net income</b>  | <b>6,033</b>          | <b>6,543</b>          | <b>-43,735</b>           |
| <b>Other comprehensive income</b>  |                       |                       |                          |
| Items that may be reclassified to the income statement                             |                       |                       |                          |
| Exchange rate differences  | 7,418                 | 5,649                 | -16,410                  |
| Tax attributable to items that have been transferred, or can be transferred to net | -                     | -465                  | 0                        |
| <b>Total other comprehensive income</b>  | <b>7,418</b>          | <b>5,184</b>          | <b>-16,410</b>           |
| <b>Total comprehensive income</b>  | <b>13,451</b>         | <b>11,727</b>         | <b>-60,145</b>           |
| <b>Attributable to</b>   |                       |                       |                          |
| Parent Company's shareholders  | 13,451                | 11,727                | -60,145                  |

## Condensed consolidated statement of financial position

| SEK Thousands   | 210331           | 201231           |
|---|------------------|------------------|
| <b>ASSETS</b>   |                  |                  |
| Goodwill  | 227,348          | 223,938          |
| Capitalized development expenditure                                     | 406,464          | 393,969          |
| Other intangible fixed assets   | 7,174            | 6,750            |
| Fixed assets  | 22,533           | 21,334           |
| Financial assets  | 39,120           | 41,088           |
| <b>Total non-current assets</b>   | <b>702,639</b>   | <b>687,079</b>   |
| Inventories   | 65,220           | 59,351           |
| Current receivables   | 49,956           | 49,643           |
| Liquid funds  | 350,324          | 354,236          |
| <b>Total current assets</b>   | <b>465,500</b>   | <b>463,230</b>   |
| <b>Total assets</b>   | <b>1,168,139</b> | <b>1,150,309</b> |
| <b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>                             |                  |                  |
| Shareholders' equity, attributable to the Parent Company's shareholders | 1,021,922        | 1,008,461        |
| Long-term interest-bearing liabilities                                  | 2,160            | 1,474            |
| Long-term non-interest-bearing liabilities                              | 68,376           | 66,314           |
| Short-term interest-bearing liabilities                                 | 4,740            | 5,738            |
| Short-term non-interest-bearing liabilities                             | 70,941           | 68,322           |
| <b>Total shareholders' equity and liabilities</b>                       | <b>1,168,139</b> | <b>1,150,309</b> |

## Condensed consolidated cash flow statements

|  | January-March<br>2021 | January-March<br>2020 | January-December<br>2020 |
|--|-----------------------|-----------------------|--------------------------|
| Income after financial items                 | 8,264                 | 6,574                 | -57,263                  |
| Adjustment for items not affecting cash flow | -1,159                | 1,373                 | 49,355                   |
| Paid taxes                                   | -272                  | -807                  | 142                      |
| Change in inventories                        | -1,620                | -5,173                | -14,155                  |
| Change in trade receivables                  | 2,665                 | 13,635                | 20,584                   |
| Change in trade payables                     | 2,446                 | -6,373                | -10,929                  |
| <b>Cash flow from operating activities</b>   | <b>10,324</b>         | <b>9,229</b>          | <b>-12,266</b>           |
| Cash flow from investing activities          | -19,505               | -15,852               | -266,532                 |
| Cash flow from financing activities          | -1,059                | -1,489                | 482,768                  |
| <b>Cash flow for the period</b>              | <b>-10,240</b>        | <b>-8,112</b>         | <b>203,970</b>           |
| Liquid funds at beginning of period          | 354,236               | 159,946               | 159,946                  |
| Exchange rate difference in liquid funds     | 6,328                 | 6,774                 | -9,680                   |
| <b>Liquid funds at end of period</b>         | <b>350,324</b>        | <b>158,608</b>        | <b>354,236</b>           |

## Consolidated changes in shareholders equity

| SEK Thousands  | Attributable to Parent Company's shareholders |                       |               |  | Sum<br>shareholders' equity |
|--|---|-----------------------|---------------|--|-----------------------------|
|  | Share capital                                 | Other paid in capital | Reserves      | Retained earnings<br>incl. profit for the 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 - March 2020                                |   |                       | 5,184         | 6,543  | 11,727                      |
| Share warrant program  |   | 14                    |               |  | 14                          |
| <b>Shareholders' equity as of March 31, 2020</b>                               | <b>680</b>                                    | <b>515,767</b>        | <b>21,412</b> | <b>51,403</b>                                  | <b>589,262</b>              |
| Total comprehensive income April - December 2020                               |   |                       | -21,595       | -50,277  | -71,872                     |
| Issuing of new shares after deduction of incremental costs directly related to | 54  | 489,640               |               |  | 489,694                     |
| Share warrant program  |   | 1,377                 |               |  | 1,377                       |
| <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>            |
| Other  |   | 10                    |               |  | 10                          |
| Total comprehensive income January - March 2021                                |   |                       | 7,418         | 6,033  | 13,451                      |
| <b>Shareholders' equity as of March 31, 2021</b>                               | <b>734</b>                                    | <b>1,006,794</b>      | <b>7,235</b>  | <b>7,159</b>                                   | <b>1,021,922</b>            |



## Condensed Consolidated statement of net income per quarter

| SEK Thousands                                      | 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 | Apr-Jun<br>2019 |
|--|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Net sales  | 58,325          | 60,277          | 42,736          | 30,393          | 46,455          | 62,416          | 54,334          | 56,437          |
| Cost of goods sold                                 | -15,645         | -18,920         | -9,602          | -7,291          | -11,073         | -16,710         | -15,791         | -14,789         |
| <b>Gross income</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>   | <b>41,648</b>   |
| Selling expenses                                   | -19,696         | -19,229         | -13,470         | -12,360         | -14,840         | -18,372         | -14,376         | -15,957         |
| Administrative expenses                            | -11,033         | -11,163         | -8,462          | -5,069          | -5,648          | -7,152          | -6,029          | -6,148          |
| Research and development costs                     | -15,529         | -15,886         | -11,233         | -12,186         | -16,873         | -17,964         | -16,827         | -12,898         |
| Other operating revenues and expenses              | 6,761           | -9,406          | -18,631         | -6,196          | 2,002           | -622            | 966             | -4,716          |
| <b>Operating income</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>    | <b>1,929</b>    |
| Financial income and expenses                      | 5,081           | -11,610         | -481            | -6,047          | 6,550           | -3,838          | 3,210           | 527             |
| <b>Income after financial items</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>    | <b>2,456</b>    |
| Taxes  | -2,231          | 6,363           | 4,457           | 2,738           | -30             | 340             | -558            | -229            |
| <b>Net income</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>2,227</b>    |
| <b>Attributable to</b>                             |                 |                 |                 |                 |                 |                 |                 |                 |
| Parent Company's shareholders                      | 6,033           | -19,575         | -14,685         | -16,018         | 6,543           | -1,902          | 4,929           | 2,227           |
| Earnings per share, SEK                            | 0.21            | -0.68           | -0.51           | -0.60           | 0.25            | -0.07           | 0.19            | 0.08            |
| Earnings per share, SEK <sup>2)</sup>              | 0.20            | -0.67           | -0.51           | -0.60           | 0.25            | -0.07           | 0.18            | 0.08            |
| Average number of outstanding shares               | 28,719,136      | 28,719,136      | 28,601,434      | 26,600,496      | 26,600,496      | 26,600,496      | 26,600,496      | 26,532,296      |
| Average number of outstanding shares <sup>2)</sup> | 29,444,136      | 29,327,136      | 28,975,434      | 26,600,496      | 26,600,496      | 26,879,496      | 26,879,496      | 26,879,496      |
| Number of shares at closing day                    | 28,719,136      | 28,719,136      | 28,719,136      | 26,600,496      | 26,600,496      | 26,600,496      | 26,600,496      | 26,600,496      |
| Number of shares at closing day <sup>2)</sup>      | 29,444,136      | 29,444,136      | 29,093,136      | 26,600,496      | 26,600,496      | 26,879,496      | 26,879,496      | 26,879,496      |
| <b>EBITDA (Operating income before</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>    | <b>8,055</b>    |
| Depreciation and amortization on                   | <b>-5,470</b>   | <b>-5,349</b>   | <b>-4,114</b>   | <b>-4,107</b>   | <b>-4,115</b>   | <b>-4,107</b>   | <b>-4,099</b>   | <b>-3,618</b>   |
| Depreciation and amortization on                   | <b>-2,554</b>   | <b>-2,473</b>   | <b>-3,318</b>   | <b>-3,150</b>   | <b>-3,412</b>   | <b>-2,776</b>   | <b>-2,649</b>   | <b>-2,508</b>   |
| <b>Operating income</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>    | <b>1,929</b>    |

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

<sup>2)</sup> After dilution

## Consolidated statement of total comprehensive income per quarter

| SEK Thousands   | 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 | Apr-Jun<br>2019 |
|---|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| <b>Net income</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>2,227</b>    |
| <b>Other comprehensive income</b>   |                 |                 |                 |                 |                 |                 |                 |                 |
| Items that may be reclassified to the income statement:                                   |                 |                 |                 |                 |                 |                 |                 |                 |
| Exchange rate differences   | 7,418           | -13,179         | -3,654          | -5,226          | 5,649           | -3,691          | 4,531           | 30              |
| Tax attributable to items that have been transferred, or can be transferred to net income | -               | -153            | 299             | 319             | -465            | 343             | -487            | -20             |
| <b>Total other comprehensive income</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>10</b>       |
| <b>Total comprehensive income</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>2,237</b>    |
| <b>Attributable to</b>  |                 |                 |                 |                 |                 |                 |                 |                 |
| Parent Company's shareholders   | 13,451          | -32,907         | -18,040         | -20,925         | 11,727          | -5,250          | 8,973           | 2,237           |

## Consolidated key ratios

| SEK Thousands                       | January-March<br>2021 | January-March<br>2020 | January-December<br>2020 |
|-------------------------------------|-----------------------|-----------------------|--------------------------|
| Gross margin non-Durable goods, %   | 75                    | 79                    | 77                       |
| Gross margin, %                     | 73                    | 76                    | 74                       |
| EBITDA, %                           | 19                    | 16                    | -9                       |
| EBITDA (adjusted), %                | 11                    | 11                    | 11                       |
| Operating margin, %                 | 5                     | 0                     | -25                      |
| Net margin, %                       | 5                     | 14                    | -24                      |
| Equity/assets ratio, %              | 87                    | 91                    | 88                       |
| Income per share, SEK               | 0.21                  | 0.25                  | -1.61                    |
| Shareholders' equity per share, SEK | 35.58                 | 22.15                 | 35.11                    |
| Share price on closing day, SEK     | 274.10                | 99.10                 | 314.00                   |
| Market cap on closing day, MSEK     | 7,872                 | 2,636                 | 9,018                    |

## Condensed income statement for the parent company

| SEK Thousands                         | January-March<br>2021 | January-March<br>2020 | January-December<br>2020 |
|---------------------------------------|-----------------------|-----------------------|--------------------------|
| Net sales                             | 38,942                | 33,174                | 134,122                  |
| Cost of goods sold                    | -4,324                | -9,106                | -36,107                  |
| <b>Gross income</b>                   | <b>34,618</b>         | <b>24,068</b>         | <b>98,015</b>            |
| Selling expenses                      | -9,946                | -8,633                | -36,675                  |
| Administrative expenses               | -8,262                | -5,017                | -27,602                  |
| Research and development expenses     | -13,113               | -14,208               | -65,268                  |
| Other operating revenues and expenses | -468                  | 38                    | -10,074                  |
| <b>Operating income</b>               | <b>2,829</b>          | <b>-3,752</b>         | <b>-41,604</b>           |
| Financial income and expenses         | 5,375                 | 8,927                 | -10,609                  |
| <b>Income after financial items</b>   | <b>8,204</b>          | <b>5,175</b>          | <b>-52,213</b>           |
| Year end dispositions                 | -                     | -                     | 4,200                    |
| Taxes                                 | -2,546                | -                     | 9,577                    |
| <b>Net income</b>                     | <b>5,658</b>          | <b>5,175</b>          | <b>-38,436</b>           |

The parent company has no items to be recognized in other comprehensive income and therefore no statement of total comprehensive income has been presented. Depreciation during the period amounts to SEK 4 868 (5 015) thousands.

## Condensed balance sheet for the parent company

| SEK Thousands                                     | 210331           | 201231           |
|---|------------------|------------------|
| <b>ASSETS</b>                                     |                  |                  |
| Intangible fixed assets                           | 256,529          | 245,777          |
| Property, plant and equipment                     | 6,587            | 5,902            |
| Financial assets                                  | 463,001          | 453,598          |
| <b>Total non-current assets</b>                   | <b>726,117</b>   | <b>705,277</b>   |
| Inventories                                       | 23,863           | 16,561           |
| Current receivables                               | 21,538           | 25,602           |
| Cash and bank                                     | 313,478          | 333,318          |
| <b>Total current assets</b>                       | <b>358,879</b>   | <b>375,481</b>   |
| <b>Total assets</b>                               | <b>1,084,996</b> | <b>1,080,758</b> |
| <b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>       |                  |                  |
| Shareholders' equity                              | 1,006,475        | 1,000,817        |
| Untaxed reserves                                  | -                | -                |
| Provisions  | 1,307            | 1,311            |
| Long-term non-interest-bearing liabilities        | 41,973           | 41,392           |
| Short-term non-interest-bearing liabilities       | 35,241           | 37,238           |
| <b>Total shareholders' equity and liabilities</b> | <b>1,084,996</b> | <b>1,080,758</b> |

# Supplementary notes

Disclosures in accordance with IAS 34.16A occur in the financial statements and the related notes, as well as elsewhere in parts of 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 for 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 acquisition value amount to SEK 400 million (204) and SEK 71 million (43) 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 recognises a liability of SEK 42 million (-), in respect of an additional purchase price linked to acquisitions, at fair value.

## Note 3. Koncernens rörelsesegment

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 for use within organ perfusion.

| SEK Thousands           | January-March     |               |               |            |                    |               |
|-------------------------|-------------------|---------------|---------------|------------|--------------------|---------------|
|                         | Non-Durable goods |               | Durable goods |            | Total consolidated |               |
|                         | 2021              | 2020          | 2021          | 2020       | 2021               | 2020          |
| Net sales               | 54,861            | 44,186        | 3,464         | 2,269      | 58,325             | 46,455        |
| Cost of goods sold      | -13,467           | -9,099        | -2,178        | -1,974     | -15,645            | -11,073       |
| <b>Gross income</b>     | <b>41,394</b>     | <b>35,087</b> | <b>1,286</b>  | <b>295</b> | <b>42,680</b>      | <b>35,382</b> |
| <b>Gross margin (%)</b> | <b>75</b>         | <b>79</b>     | <b>37</b>     | <b>13</b>  | <b>73</b>          | <b>76</b>     |

## Note 4. Other operating revenues and expenses

| SEK Thousands  | 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 | April-June<br>2019 |
|--|-----------------|-----------------|------------------|--------------------|-------------------|-----------------|------------------|--------------------|
| Cost of cash-based incentive program for employees outside | 7,084           | -8,332          | -12,469          | -                  | 2,541             | 237             | 2,253            | -4,000             |
| Cost of reorganization                                     | -               | -               | -5,375           | -4,498             | -                 | -               | -                | -                  |
| Other  | -323            | -1,074          | -786             | -1,698             | -539              | -859            | -1,287           | -716               |
| <b>Total</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>       | <b>-4,716</b>      |

# Reconciliation of alternative performance measures

This report includes key figures that are not defined in IFRS, but is included in the report as management believes that this data facilitates 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-March<br>2021 | January-March<br>2020 | January-<br>December<br>2020 |
|---|-----------------------|-----------------------|------------------------------|
| <b>Operating income</b>   | <b>3,183</b>          | <b>23</b>             | <b>-45,675</b>               |
| Depreciation and amortization on intangible assets                    | 5,470                 | 4,115                 | 17,685                       |
| Depreciation and amortization on tangible assets                      | 2,554                 | 3,412                 | 12,353                       |
| <b>EBITDA (Operating income before depreciation and amortization)</b> | <b>11,207</b>         | <b>7,550</b>          | <b>-15,637</b>               |

## Gross margin

| SEK Thousands             | January-March<br>2021 | January-March<br>2020 | January-<br>December<br>2020 |
|---------------------------|-----------------------|-----------------------|------------------------------|
| Operating income          |                       |                       |                              |
| <i>Net sales</i>          | 58,325                | 46,455                | 179,861                      |
| Operating expenses        |                       |                       |                              |
| <i>Cost of goods sold</i> | -15,645               | -11,073               | -46,886                      |
| <b>Gross income</b>       | <b>42,680</b>         | <b>35,382</b>         | <b>132,975</b>               |
| <b>Gross margin %</b>     | <b>73</b>             | <b>76</b>             | <b>74</b>                    |

## Gross margin non-durable goods

| SEK Thousands                            | January-March<br>2021 | January-March<br>2020 | January-<br>December<br>2020 |
|--|-----------------------|-----------------------|------------------------------|
| Operating income                         |                       |                       |                              |
| <i>Net sales of non-Durable goods</i>    | 54,861                | 44,186                | 169,425                      |
| <b>Operating expenses</b>                |                       |                       |                              |
| <i>Cost of non-Durable goods sold</i>    | -13,467               | -9,099                | -38,980                      |
| <b>Gross income, non-Durable goods</b>   | <b>41,394</b>         | <b>35,087</b>         | <b>130,445</b>               |
| <b>Gross margin, non-Durable goods %</b> | <b>75</b>             | <b>79</b>             | <b>77</b>                    |

When calculating the 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. The gross margin thus indicates the proportion of net sales traded in profit after the cost of the goods sold, and is affected by factors such as pricing, raw material and manufacturing costs, inventory write-downs and exchange rate developments.

## Equity/Assets ratio

| SEK Thousands                | 210331    | 201231    |
|------------------------------|-----------|-----------|
| Shareholders' equity         | 1,021,922 | 1,008,461 |
| Total assets                 | 1,168,139 | 1,150,309 |
| <b>Equity/assets ratio %</b> | <b>87</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 is calculated by placing equity in relation to the total assets and is thus 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 excluded separately from durable goods. |
| <b>Gross margin, %</b>                        | Gross income as a percentage of the 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.          | Operating income before depreciation and amortization as a percentage of net sales for the period.  |
| <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>                          | Income for the period 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 to 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 at closing day                         | 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 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 equity 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 American 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 the supply of oxygen and necessary nutrients during transport to the recipient  |
| <b>In vivo</b>   | Biological processes in living cells and tissues when they are in their natural place in intact organisms.  |
| <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. Within the business area Thoracic 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. Within the business area Abdominal 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>Medical device</b>                                  | Comprises devices used to diagnose a disease or treat a disease and as rehabilitation.  |
| <b>OPO or Organ Procurement Organization</b>           | In the United States, an organ procurement organization (OPO) is a non-profit organization that is 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 Class III medical devices. Class III devices support or sustain human life, are of substantial importance in preventing impairment of human health, or potentially present an unreasonable risk of illness or injury.  |
| <b>Preclinical study</b>                               | Research performed before a drug or method of treatment is sufficiently documented to be studied in humans, for example the testing of substances in tissue samples and subsequent testing in experimental animals.   |
| <b>Preservation</b>                                    | Storage and maintenance of an organ outside the body before transplantation   |
| <b>Reimbursement</b>                                   | Reimbursement is relevant within the health insurance system for healthcare providers to be paid 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 kept cold during transport and before transplantation. Within the business area Thoracic this includes Perfadex® Plus as well as other products and services related to the use of that product. |
| <b>Other Sales</b>          | In terms of product category, Other sales refers to income relating to freight, service and training.  |
| <b>Xeno-transplantation</b> | Transplantation of living cells, tissues or organs from one species to another.  |

# Extending horizons



XVIVO  
Box 53015  
SE-400 14 Göteborg  
Sweden

[info@xvivoperfusion.com](mailto:info@xvivoperfusion.com)  
[xvivoperfusion.com](http://xvivoperfusion.com)