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# Interim Report January – September 2021

XVIVO Perfusion AB (publ)

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# XVIVO

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## Interim Report January – September 2021

### Third quarter 2021 (Jul 1 - Sep 30)

- Net sales amounted to SEK 54.9 million (42.7), corresponding to an increase of 29 percent in SEK and 31 percent in local currencies. Net sales of non-durable goods amounted to SEK 48.9 million (42.3), corresponding to an increase of 16 percent in SEK and 18 percent in local currencies.
- Machine perfusion accounted for 53 percent (41) of net sales.
- Adjusted operating profit before depreciation and amortization (EBITDA) amounted to SEK 5.3 million (9.3), corresponding to an adjusted EBITDA margin of 10 percent (22). Reported EBITDA amounted to SEK 4.2 million (-11.2), corresponding to an EBITDA margin of 8 percent (-26).
- Adjusted operating profit (EBIT) amounted to SEK -2.9 million (1.8). Reported EBIT amounted to SEK -4.0 million (-18.7).
- Net profit amounted to SEK -1.1 million (-14.7). Earnings per share amounted to SEK -0.04 (-0.5).
- Cash and cash equivalents at the end of the quarter amounted to SEK 284.5 million (608.4).

### Significant events during the quarter

- Strategic focus areas were presented at XVIVO's first Capital Markets Day. These will support the company's goal to become the leading player in the transplant industry during the strategy period 2022-2026.
- XVIVO participated with a strong presence at the ESOT Congress in Milan. The focus of the congress on machine perfusion was very evident.
- A pilot project in advanced data analysis from liver perfusion was initiated with UMC Groningen as a partner.

### Key ratios

TSEK	January- September 2021	January- September 2020	July-September 2021	July-September 2020	Full year 2020
Net sales	172 523	119 584	54 935	42 736	179 861
Non-Durable goods	160 013	114 498	48 893	42 309	169 425
Durable goods	12 510	5 086	6 042	427	10 436
Machine perfusion share of net sales, %	52	36	53	41	43
Gross margin, %	73	77	69	78	74
Non-Durable goods	75	79	73	78	77
Durable goods	42	19	33	58	24
EBITDA	13 855	-9 131	4 181	-11 229	-15 637
EBITDA (adjusted) <sup>1)</sup>	19 976	13 370	5 306	9 315	20 172
Earnings per share, SEK	-0,14	-0,91	-0,04	-0,51	-1,61
Cash flow from operating activities	-11 497	9 733	-8 455	-1 882	-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 -1.1 (-20.5) million for the quarter. Net adjustment for the period totals SEK -6.1 (-22.5) million.

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

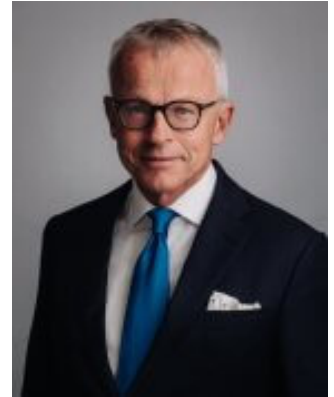
- Net sales amounted to SEK 172.5 million (119.6), corresponding to an increase of 44 percent in SEK and 54 percent in local currencies. Net sales of non-durable goods amounted to SEK 160.0 million (114.5), corresponding to an increase of 40 percent in SEK and 50 percent in local currencies.
- Machine perfusion accounted for 52 percent (36) of net sales.
- Adjusted operating profit before depreciation and amortization (EBITDA) amounted to SEK 20.0 million (13.4), corresponding to an adjusted EBITDA margin of 12 percent (11). Reported EBITDA amounted to SEK 13.9 million (-9.1), corresponding to an EBITDA margin of 8 percent (-8).
- Adjusted operating profit (EBIT) amounted to SEK -4.1 million (-8.8). Reported EBIT amounted to SEK -10.2 million (-31.5).
- Net profit amounted to SEK -4.0 million (-24.2). Earnings per share amounted to SEK -0.14 (-0.91).
- Cash and cash equivalents at the end of the period amounted to SEK 284.5 million (608.4).

### Significant events in the period

- Publication in reputable scientific journal The New England Journal of Medicine shows significant benefits of oxygenated cold machine perfusion prior to liver transplantation.
- The 510(k) application for Kidney Assist Transport was submitted to the FDA.
- Guidelines from NICE supporting EVLP as the standard lung preservation procedure were issued in the UK.

# New strategy launched

XVIVO had an eventful and intensive third quarter. In August, the company launched a new strategy for the coming five years to support our goal of becoming the global leader in the transplantation industry for all major organs. The strategy focuses on five areas: becoming the global leader in abdominal (kidney and liver); commercializing our unique heart preservation system; increasing penetration of machine perfusion; ensuring cost reimbursement for machine perfusion on key geographical markets and, last but not least; making China our second biggest market in terms of sales during the strategy period.



Dag Andersson, CEO

Total sales were SEK 55 million (43) in the third quarter, corresponding to an increase of 31 percent in local currency. The increase was attributable to the acquisition of Organ Assist which was completed in October last year. Whilst the business area Abdominal presented its strongest quarter for this year, business area Thoracic showed a weaker performance.

Thoracic's sales amounted to SEK 42 million (43) and was affected by low lung transplantation activity in the US due to the continued impact of the Delta variant on intensive care. The first half-year was strong in the US, although after the downturn in the third quarter lung transplantation volumes in the US have now returned to 2020 levels and are 6 percent below 2019. The number of lung transplants in the US during the third quarter was 586, which is a decrease compared to the second quarter by 18 percent. At the beginning of September, nearly 100,000 patients were treated for Covid-19 in U.S. hospitals, and at the beginning of the quarter, the number of patients was only 13,000. At the time of writing, the figure is down to 55,000 and the trend is thus going in the right direction again. We expect a gradual increase in the number of transplants in all markets as the number of new Covid-19 cases decreases.

Lung Bioengineering bought their fourth XPS machine in September, which was pleasing. The company's centralized model for lung perfusion, which supplies several US hospitals with perfusion services, is very successful and something that we expect to see also outside the US. Two new EVLP centers will shortly be activated for lung perfusion in the UK and Germany. This represents a significant advance on both markets, as clinics in these countries have previously mainly used our preservation solution, Perfadex® Plus.

Abdominal presented a strong quarter. Sales was SEK 13 million (-). In the third quarter, hospitals in Abdominal's main markets in southern and central Europe were under less strain than in the US. When it comes to our goal of launching Kidney Assist Transport on the US market, we await final decision on our 510(k) application. We hope to begin a selective launch in the fourth quarter.

XVIVO is presenting another quarter with strong margins. Thoracic's gross margin totaled 78 percent (78) and Abdominal 53 percent (-). Although, raw materials costs are expected to increase in many sectors, including ours, I am confident about our ability to protect Thoracic's margins and significantly improve margins in Abdominal over time. Our unique and world leading products shall generate strong margins.

Another center is now up and running in the European heart preservation study, which means that six centers now include patients in the study. Several further centers are expected to start up in the fourth quarter.

XVIVO has taken the first steps on a digital transformation journey through a partnership with UMC Groningen, where we are developing a technology for the analysis of data collected from liver perfusion machines in a new pilot project. We have also initiated a similar collaboration with a leading US transplant clinic, which aims to develop a technology for analysis of lung transplantation data.

In conclusion, we completed several important marketing activities in the third quarter. In September, XVIVO hosted its first capital markets day. Our five-year strategic plan was presented, which also includes our ambition to achieving an EBIT margin of 20% and EBITDA of 30% in the strategy period.

XVIVO also participated in the ESOT Congress (European Society for Organ Transplantation) in Milan. We had a very strong presence, including a successful symposium on machine perfusion. It was clear at ESOT that it is now generally accepted that machine perfusion is key to ensuring more successful organ transplants, which means that we are well positioned to drive progress in this area on key geographical markets globally.

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.

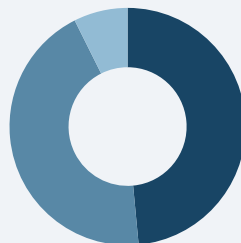
## Target

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

# >160,000

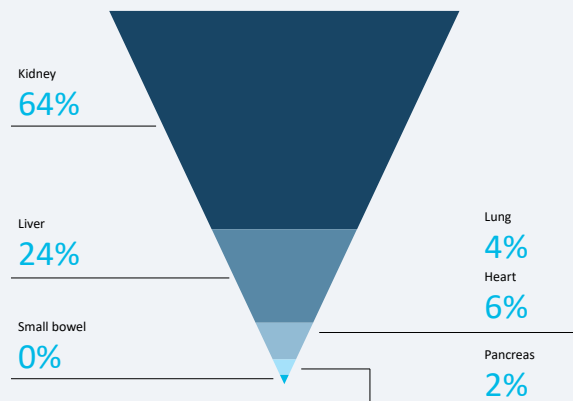
Organs transplanted per year, representing ~10% of the need\*

\*WHO estimate



NET SALES PER GEOGRAPHICAL REGION IN THE QUARTER

- Americas (49%)
- EMEA (44%)
- APAC (7%)



## Strategic drivers

### 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-September 2021	January-September 2020	July-September 2021	July-September 2020	January-December 2020
Net Sales non-Durable Goods	160 013	114 498	48 893	42 309	169 425
Net Sales Durable Goods	12 510	5 086	6 042	427	10 436
<b>Net Sales Total</b>	<b>172 523</b>	<b>119 584</b>	<b>54 935</b>	<b>42 736</b>	<b>179 861</b>
Cost of Goods non-Durable Goods	-40 148	-23 837	-12 974	-9 422	-38 980
Cost of Goods Durable goods	-7 213	-4 129	-4 026	-180	-7 906
Cost of Goods Total	-47 361	-27 966	-17 000	-9 602	-46 886
Gross income non-Durable Goods	119 865	90 661	35 919	32 887	130 445
Gross margin non-Durable Goods, %	75%	79%	73%	78%	77%
Gross income Durable Goods	5 297	957	2 016	247	2 530
Gross margin Durable Goods, %	42%	19%	33%	58%	24%
Gross income Total	125 162	91 618	37 935	33 134	132 975
Gross margin Total, %	73%	77%	69%	78%	74%
Selling expenses	-63 653	-40 670	-23 344	-13 470	-59 899
Administrative expenses	-34 691	-19 179	-9 053	-8 462	-30 342
Research and development expenses	-40 020	-40 292	-10 457	-11 233	-56 178
Other operating revenues and expenses <sup>1)</sup>	3 004	-22 825	888	-18 631	-32 231
<b>Operating Income</b>	<b>-10 198</b>	<b>-31 347</b>	<b>-4 031</b>	<b>-18 661</b>	<b>-45 675</b>
Amortization and depreciation cost of goods sold	-259	-642	-90	-211	-462
Depreciation administrative expenses	-2 542	-2 400	-896	-880	-3 154
Amortization of research and development expenses	-17 455	-15 063	-5 894	-5 038	-21 133
Depreciation other operative expenses	-3 797	-4 111	-1 332	-1 303	-5 289
<b>EBITDA (Operating income before depreciation and amortization)</b>	<b>13 855</b>	<b>-9 131</b>	<b>4 181</b>	<b>-11 229</b>	<b>-15 637</b>
EBITDA, %	8%	-8%	8%	-26%	-9%
<b>EBITDA (adjusted) <sup>2)</sup></b>	<b>19 976</b>	<b>13 370</b>	<b>5 306</b>	<b>9 315</b>	<b>20 172</b>
EBITDA (adjusted), %	12%	11%	10%	22%	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 -1.1 (-20.5) million for the quarter. Net adjustment for the period totals SEK -6.1 (-22.5) million.

# Summary

## The quarter July - September 2021

### Net sales and income

We can conclude that the Covid-19 pandemic continued to affect the number of transplants globally in the third 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 than ever are now waiting for a new organ.

Sales development during the quarter was negatively impacted by a decrease in the number of lung transplants in the company's main market, the US. Net sales increased by 29 percent during the quarter, amounting to SEK 54.9 million (42.7). This corresponds to an increase of 31 percent in local currencies. Net sales of non-durable goods increased by 16 percent, amounting to SEK 48.9 million (42.3). The increase corresponds to 18 percent in local currency. The sales growth for the quarter consists of revenues from the Abdominal business area, which was not included in the comparison quarter. For the business area Thoracic, sales were in line with last years quarter.

Machine perfusion accounted for 53 percent (41) 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 69 percent (78) and gross margin for non-durable goods amounted to 73 percent (78). The decrease is explained by the fact that the comparison quarter does not include the Abdominal business area, which at present displays 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 -0.1 million and was charged with integration costs of SEK -1.0 million. Adjusted for these items totaling SEK -1.1 million (-20.5), EBITDA amounts to SEK 5.3 million (9.3), corresponding to an adjusted EBITDA margin of 10 percent (22). Reported EBITDA amounted to SEK 4.2 million (-11.2), corresponding to an EBITDA margin of 8 percent (-26).

Operating income (EBIT) adjusted for the above-mentioned items amounted to SEK -2.9 million (1.8). Reported EBIT amounted to SEK -4.0 million (-18.7).

Selling expenses in relation to sales amounted to 42 percent (32) for the quarter. R&D expenses amounted to 19 percent (26) of sales. Administrative expenses amounted to 16 percent (20) of sales.

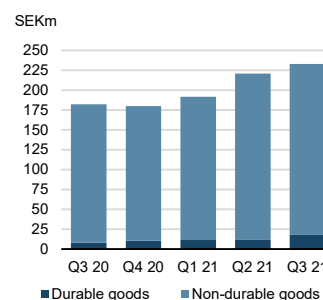
The quarter was charged with costs for the integration of Organ Assist. The acquisition was consolidated into XVIVO on October 1, 2020, and since then, the focus has primarily been on integrating the sales and administration functions. During the third quarter, integration costs affected sale expenses by SEK 0.2 million (-) and administration expenses by SEK 0.8 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 fourth quarter and the integration costs from the acquisition are subsequently expected to cease.

Other operating income and operating expenses amounted to SEK -0.9 million (-18,6) during the quarter. The item primarily consists of currency conversion effects and depreciation. See Note 4 for more information.

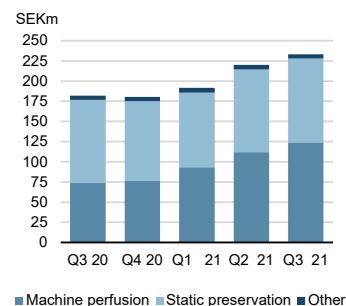
Net financial income and expenses for the quarter amounted to SEK 3.0 million (-0.5). This was mainly due to negative currency conversion effects relating to the Group's cash and cash equivalents.

During the quarter, SEK 18.0 million (13.1) 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 5.0 million (3.9) during the quarter, of which SEK 3.9 million (3.9) 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.

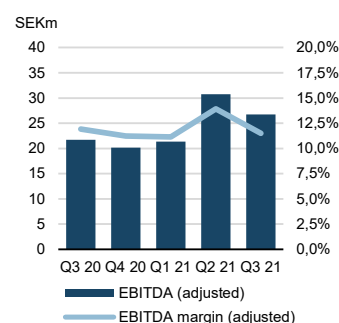
Net sales per segment (R12)



Net sales per product category (R12)



EBITDA och EBITDA-margin (adjusted, R12)



## Cash flow

Cash flow from operating activities for the quarter amounted to SEK -8.5 million (-1.8) and was mainly affected by an increase in the capital tied-up in inventories due to increased production of XPS machines and Kidney Assist Transport machines. Cash flow from investment activities amounted to SEK -20.2 million (-14.6), of which SEK -18.0 million (-13.7) was invested in intangible assets and SEK -1.9 million (-0.9) was invested in tangible assets. Cash flow from financing activities amounted to SEK -1.4 million (486.1). Exchange differences in cash and cash equivalents had a positive impact on cash flow for the quarter of SEK 3.1 million (-1.2). Cash and cash equivalents at the end of the quarter amounted to SEK 284.5 million (608.4).

## Significant events during the quarter

### Strategic focus areas presented at XVIVO's first Capital Markets Day

In September, XVIVO held its first capital markets day in front of audiences present both physically and digitally. The CEO together with other senior executives presented the company's strategic focus areas for 2022-2026 and market insights were conveyed by both internal and external presenters. During the strategy period, XVIVO will become the leading player in the transplant industry. This will be done by delivering in five strategic focus areas: 1) Become a global leader in Abdominal, 2) Launch a market-leading heart preservation system, 3) Increase penetration of machine perfusion for all organs, 4) Ensure inclusive reimbursement in key geographic markets, and 5) Develop China into XVIVO's second largest market.

### Strong presence at the ESOT Congress in Milan

This year's edition of the European Society for Organ Transplantation (ESOT) congress took place in Milan in the end of August. It was the first major congress held physically since the pandemic outbreak and the event was therefore highly awaited. It was also the first time that XVIVO had the opportunity to demonstrate its overall product portfolio for both Thoracic and Abdominal. Furthermore, XVIVO organized a successful symposium on the topic machine perfusion.

### Pilot project within advanced data analysis started with UMC Groningen as partner

XVIVO and University Medical Center Groningen (UMCG) have agreed to jointly conduct a pilot project in advanced analysis using liver perfusion data from XVIVO's liver perfusion machine, Liver Assist. The project, called XCEPT, aims to extract data from perfusion to enable advanced analysis of organs prior to transplantation. The analysis will help surgical teams make a more data-driven decision and increase the number of successful liver transplants.

## The period January - September 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 than ever are now waiting for a new organ.

In XVIVO's main market, the US, the first half of the year showed a strong recovery in the number of lung transplants, but after the decline in the third quarter, this year's transplant volume in the US is now back to 2020 levels and 6 percent below 2019 levels. In Europe, development has been more stable, but regional variation remains high. The number of transplants during 2021 is on the same level as 2020, but just below 2019.

Net sales increased by 44 percent in the period, amounting to SEK 172.5 million (119.6). That corresponds to an increase of 54 percent in local currencies. 30 percent of this increase comes from acquired growth. Net sales of non-durable goods increased by 40 percent, amounting to SEK 160.0 million (114.5). The increase corresponds to 50 percent in local currency.

Machine perfusion accounted for 52 percent (36) 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 73 percent (77) and gross margin for non-durable goods amounted to 75 percent (79). The decrease is explained by the fact that the comparative period does not include the Abdominal business area, which at present displays lower margins 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 3.1 million and was charged with integration costs by SEK -5.8 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 -6.1 million (-22.5), EBITDA amounts to SEK 20.0 million (13.4), corresponding to an adjusted EBITDA margin of 12 percent (11). Reported EBITDA amounted to SEK 13.9 million (-9.1), corresponding to an EBITDA margin of 8 percent (-8).

Operating income (EBIT) adjusted for the above-mentioned items amounted to SEK -4.1 million (-8.8). Reported EBIT amounted to SEK -10.2 million (-31.3).

Selling expenses as a proportion of sales amounted to 37 percent (34) in the period. R&D expenses amounted to 23 percent (34) of sales. Administrative expenses amounted to 20 percent (16) 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 2.5 million (-) and administration expenses by SEK 3.3 million (-).

Other operating income and operating expenses amounted to SEK 3.0 million (-22.8) in the period. The item primarily consists of positive effects from the cash-based incentive program for employees abroad of SEK 3.1 million. The remainder primarily consists of currency conversion effects and depreciation. See Note 4 for more information.

Net financial income and expenses for the period amounted to SEK 6.6 million (0). The positive contribution is mainly due to positive currency conversion effects relating to the Group's cash and cash equivalents.

During the period, SEK 55.1 million (41.6) 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 15.9 million (11.6) in the period, of which SEK 11.6 million (11.6) 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.

Net sales

**SEK 173  
million**

Gross margin

**73%**

Adjusted EBITDA

**12%**



## Cash flow

Cash flow from operating activities in the period amounted to SEK -11.5 million (9.7), primarily due to an increase in capital tied up in inventories due to increased production of XPS machines and Kidney Assist Transport machines. 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 -62.5 million (-44.3), of which SEK -55.1 million (-42.5) was invested in intangible assets and SEK -7.1 million (-1.8) was invested in tangible assets. Cash flow from financing activities amounted to net SEK -2.3 million (484.0). Exchange rate differences in the period had a positive cash flow effect of SEK 6.6 million (-1.4). Cash and cash equivalents at the end of the period amounted to SEK 284.5 million (608.4).

## Financing

XVIVO's operations shall be conducted with a sustainable and efficient capital structure. The company's equity ratio is strong and amounted to 88 percent (93) 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

### 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.

### 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 September 2021, there were a total of 28,752,397 shares and votes in the company.

### 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 machine used for oxygenated perfusion in the trial is CE-marked. XVIVO's goal is to have decided, in dialogue with the FDA, before the end of the year on the regulatory way forward.

### 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-September 2021	January-September 2020	July-September 2021	July-September 2020
Net sales	138 558	119 584	42 270	42 736
Non-Durable goods	132 748	114 498	39 940	42 309
Durable goods	5 810	5 086	2 330	427
Gross margin, %	78	77	75	78
Non-Durable goods	80	79	78	78
Durable goods	34	19	20	-863

### The quarter July - September 2021

Net sales during the quarter were in line with the previous year and amounted to SEK 42.3 million (42.7). Net sales without capital goods decreased by 6 percent to SEK 39.9 million (42.3). The number of lung transplants in the US in the third quarter was 586, which represents a decrease compared to the second quarter of 18 percent and 9 percent compared to the third quarter of 2020. It was gratifying that one of the company's largest customers in the US, Lung Bioengineering, bought its fourth XPS machine during the quarter. In Europe the impact of the pandemic varies between regions. Overall, sales were in line with the comparison quarter and the second quarter this year.

Machine perfusion accounted for 38 percent (41) of net sales. Static preservation and other sales accounted for the remainder of net sales.

Gross margin for the quarter was 75 percent (78). Gross margin without capital goods was 78 percent (78).

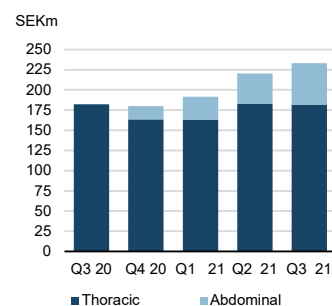
### The period January - September 2021

Net sales increased in the period compared to the corresponding period in the previous year, amounting to SEK 138.6 million (119.6) In local currencies, this represented growth of 24 percent. Net sales of non-durable goods increased by 16 percent, amounting to SEK 132.7 million (114.5). In local currencies, this represented growth of 24 percent. In total, two XPS machines were sold during the period, both in the US.

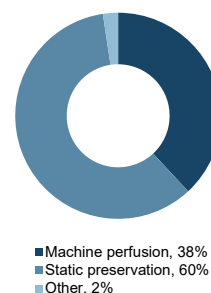
Machine perfusion accounted for 40 percent (36) of net sales. The increase was primarily driven by a recovery at the more established EVLP clinics in the United States. Static preservation and other sales accounted for the remainder of net sales.

Gross margin for the period was 78 percent (77). Gross margin excluding non-durable goods was 80 percent (79).

Net sales per business area (R12)



Net sales per product category, Thoracic (Q3)



## 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 selective markets in Europe at present, but also on smaller markets outside North America.

### Summary

SEK Thousands	January-September 2021	January-September 2020	July-September 2021	July-September 2020
Net sales	33 965	-	12 665	-
<i>Non-Durable goods</i>	27 265	-	8 953	-
<i>Durable goods</i>	6 700	-	3 712	-
Gross margin, %	51	-	50	-
<i>Non-Durable goods</i>	51	-	53	-
<i>Durable goods</i>	50	-	42	-

Net sales per product category, Abdominal (Q3)



■ Machine perfusion, 100%  
■ Static preservation, 0%  
■ Other, 0%

### The quarter July - September 2021

In Abdominal, where the customer base is currently largely focused on certain southern and central European key markets, the pandemic continued to impact sales in the quarter. Pressure on hospitals in several European countries has temporarily restricted sales. Some recovery has been noted in the third quarter, and it is gratifying that sales of durable goods amounted to SEK 3.7 million (-).

Net sales during the quarter amounted to SEK 12.7 million (-). Net sales of non-durable goods amounted to SEK 9.0 million (-). Since XVIVO's abdominal operations were acquired in the fourth quarter of 2020, comparison figures for the Group for the third quarter of 2021 are missing. However, sales were in line with the comparison quarter of the underlying business. Machine perfusion accounted for 100 percent (-) of net sales.

Gross margin of non-durable goods during the quarter amounted to 53 percent (-), an improvement compared to the first two quarters of the year.





### The period January - September 2021

Net sales during the period amounted to SEK 34.0 million (-). Net sales of non-durable goods amounted to SEK 27.3 million (-). Since XVIVO's abdominal operations were acquired in the fourth quarter of 2020, comparison figures for the Group for the period January - September 2021 are missing. The underlying business showed organic growth of 28 percent in local currencies. Machine perfusion accounted for 99 percent (-) of net sales.


Gross margin without capital goods during the period amounted to 51 percent (-). Price increases were carried out in the first quarter according to plan, but the positive effect on gross margin is largely temporarily absorbed by increased purchase prices. A supplier change is in progress and the gross margin is expected to be strengthened after regulatory approval as the new products have a lower cost of production.

# R&D Portfolio

## Development projects

Project	Description	Status
<b>Heart transplantation</b> 	<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 randomized 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, six clinics are currently actively enrolling patients in the XVIVO study. Another five clinics are in the start-up phase. During 2021, several centers contacted XVIVO requesting to participate. 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 is also in progress in Australia, where the two biggest clinics of the country are including patients.</p>
<b>Kidney transplantation</b> 	<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. An international high-quality study was published in The Lancet in the fourth quarter of 2020. The study shows significant benefits for the recipient when the kidney is transported perfused with an oxygenated solution. This is the technology unique for XVIVO.</p>	<p>The company's application for regulatory approval in the United States is in the final phase. The combination of new perfusion technology and solutions will be the focus of future research in the organ field.</p>
<b>Liver transplantation</b> 	<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. Future research in the field will focus on the combination of new perfusion technology and solutions.</p>
<b>PrimECC®</b> 	<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. Applications to include centres in Denmark, Norway and Germany in the study are under consideration by ethics committees.</p>

## Research projects

Project	Description	Status
<b>Xeno-transplantation</b> 	<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 94 people, of which 44 women and 49 men. Of these, 43 people are employed in Sweden and 51 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).

## Nomination Committee for the 2022 Annual General Meeting

The following members have been appointed to XVIVO Perfusion's Nomination Committee for the 2022 Annual General Meeting:

Henrik Blomquist, appointed by Bure Equity AB  
Thomas Ehlin, appointed by The Fourth Swedish National Pension Fund  
Caroline Sjösten, appointed by Swedbank Robur Fonder AB  
Gösta Johannesson, Chairman of the Board

The appointments have been made in accordance with the instructions regarding principles for the appointment of the company Nomination Committee which were determined at the Annual General Meeting of XVIVO Perfusion AB (publ) on April 27, 2018. The members of the Nomination Committee together represent 32 percent of the votes attached to all voting shares in the company as of August 31, 2021.

## Outlook

The extent to which the Covid-19 pandemic will affect our sales and clinical trials during the remainder of 2021 and during 2022 is largely determined by the speed of the vaccine roll-out globally, and how fast intensive care in the company's main markets in the US and Europe return to normal capacity. The fourth quarter has started in the US with a continued positive trend. The number of patients being treated for Covid-19 in US hospitals has

continued to decline and the number of lung transplants has started to rise again. 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.

During the fourth quarter of 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 the Kidney Assist Transport in the US in the fourth quarter. For Liver Assist, the goal towards the end of 2021 is to, in dialogue with the FDA, decide on the regulatory way forward in the US. In heart transplantation, the goal is to take major steps forward in the multicenter clinical studies in Europe, the US and Australia. The PrimECC® study is expected to accelerate as more clinics are now 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.

This report has been issued by the CEO on behalf of the Board.

Gothenburg, October 21, 2021

Dag Andersson  
CEO

*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 October 21, 2021 at 7.30 am.



### Financial calendar

- 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
- Interim Report January-September  
2022: Thursday, October 27, 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 Thursday, October 21, 2021.  
Telephone SWE: +46 (0)8 566 426 51  
Telephone UK: +44 3333 000804  
Telephone US: +1 6319 131422  
PIN: 13466713#



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## Review report

To the Board of Directors of XVIVO Perfusion AB (publ.)

Corp. id. 556561-0424

### Introduction

We have reviewed the condensed interim financial information (interim report) of XVIVO Perfusion AB (publ.) as of 30 September 2021 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

### Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Gothenburg 21 October 2021

KPMG AB

Daniel Haglund

Authorized Public Accountant



# Financial statements

## Condensed Consolidated Statement of Net Income

SEK Thousands	January-September 2021	January-September 2020	July-September 2021	July-September 2020	January-December 2020
Net sales	172 523	119 584	54 935	42 736	179 861
Cost of goods sold	-47 361	-27 966	-17 000	-9 602	-46 886
<b>Gross income</b>	<b>125 162</b>	<b>91 618</b>	<b>37 935</b>	<b>33 134</b>	<b>132 975</b>
Selling expenses	-63 653	-40 670	-23 344	-13 470	-59 899
Administrative expenses	-34 691	-19 179	-9 053	-8 462	-30 342
Research and development expenses	-40 020	-40 292	-10 457	-11 233	-56 178
Other operating revenues and expenses <sup>1)</sup>	3 004	-22 825	888	-18 631	-32 231
<b>Operating income</b>	<b>-10 198</b>	<b>-31 347</b>	<b>-4 031</b>	<b>-18 661</b>	<b>-45 675</b>
Financial income and expenses	6 626	22	2 956	-481	-11 588
<b>Income after financial items</b>	<b>-3 572</b>	<b>-31 325</b>	<b>-1 075</b>	<b>-19 142</b>	<b>-57 263</b>
Taxes	-465	7 165	-54	4 457	13 528
<b>Net income</b>	<b>-4 037</b>	<b>-24 160</b>	<b>-1 129</b>	<b>-14 685</b>	<b>-43 735</b>
<b>Attributable to</b>					
Parent Company's shareholders	-4 037	-24 160	-1 129	-14 685	-43 735
Earnings per share, SEK	-0,14	-0,91	-0,04	-0,51	-1,61
Earnings per share, SEK <sup>2)</sup>	-0,14	-0,89	-0,04	-0,51	-1,60
Average number of outstanding shares	28 723 201	26 639 730	28 727 266	28 601 434	27 171 352
Average number of outstanding shares <sup>2)</sup>	28 847 868	27 013 730	29 101 266	28 975 434	27 354 518
Number of shares at closing day	28 752 397	28 719 136	28 752 397	28 719 136	28 719 136
Number of shares at closing day <sup>2)</sup>	29 126 397	29 093 136	29 126 397	29 093 136	29 444 136
<b>EBITDA (Operating income before depreciation and amortization)</b>	<b>13 855</b>	<b>-9 131</b>	<b>4 181</b>	<b>-11 229</b>	<b>-15 637</b>
Depreciation and amortization on intangible assets	-15 883	-12 336	-5 278	-4 114	-17 685
Depreciation and amortization on tangible assets	-8 170	-9 880	-2 934	-3 318	-12 353
<b>Operating income</b>	<b>-10 198</b>	<b>-31 347</b>	<b>-4 031</b>	<b>-18 661</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-September 2021	January-September 2020	July-September 2021	July-September 2020	January-December 2020
<b>Net income</b>	<b>-4 037</b>	<b>-24 160</b>	<b>-1 129</b>	<b>-14 685</b>	<b>-43 735</b>
<b>Other comprehensive income</b>					
Items that may be reclassified to the income statement					
Exchange rate differences	6 877	-3 231	3 163	-3 654	-16 410
Tax attributable to items that have been or can be transferred to net income	-	153	-	299	-
<b>Total other comprehensive income</b>	<b>6 877</b>	<b>-3 078</b>	<b>3 163</b>	<b>-3 355</b>	<b>-16 410</b>
<b>Total comprehensive income</b>	<b>2 840</b>	<b>-27 238</b>	<b>2 034</b>	<b>-18 040</b>	<b>-60 145</b>
<b>Attributable to</b>					
Parent Company's shareholders	2 840	-27 238	2 034	-18 040	-60 145

## Condensed Consolidated Statement of Financial Position

SEK Thousands	210930	200930	201231
<b>ASSETS</b>			
Goodwill	226 801	65 622	223 938
Capitalized development expenditure	432 845	296 526	393 969
Other intangible fixed assets	8 696	6 427	6 750
Fixed assets	21 706	21 780	21 334
Financial assets	41 440	19 880	41 088
<b>Total non-current assets</b>	<b>731 488</b>	<b>410 235</b>	<b>687 079</b>
Inventories	78 999	53 445	59 351
Current receivables	49 374	47 042	49 643
Liquid funds	284 516	608 374	354 236
<b>Total current assets</b>	<b>412 889</b>	<b>708 861</b>	<b>463 230</b>
<b>Total assets</b>	<b>1 144 377</b>	<b>1 119 096</b>	<b>1 150 309</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
Shareholders' equity, attributable to the Parent Company's shareholders	1 012 541	1 041 891	1 008 461
Long-term interest-bearing liabilities	746	1 562	1 474
Long-term non-interest-bearing liabilities	68 478	2 719	66 314
Short-term interest-bearing liabilities	3 925	6 061	5 738
Short-term non-interest-bearing liabilities	58 687	66 863	68 322
<b>Total shareholders' equity and liabilities</b>	<b>1 144 377</b>	<b>1 119 096</b>	<b>1 150 309</b>

## Condensed Consolidated Cash Flow Statement

	January-September 2021	January-September 2020	July-September 2021	July-September 2020	January-December 2020
Income after financial items	-3 572	-31 325	-1 075	-19 141	-57 263
Adjustment for items not affecting cash flow	12 282	26 635	3 324	7 975	49 355
Paid taxes	-2 205	-1 105	-462	-726	142
Change in inventories	-12 906	-15 637	-3 454	-11 358	-14 155
Change in trade receivables	4 531	12 533	-194	-10 923	20 584
Change in trade payables	-9 627	18 632	-6 594	32 291	-10 929
<b>Cash flow from operating activities</b>	<b>-11 497</b>	<b>9 733</b>	<b>-8 455</b>	<b>-1 882</b>	<b>-12 266</b>
Cash flow from investing activities	-62 545	-44 343	-20 207	-14 597	-266 532
Cash flow from financing activities	-2 284	484 478	-1 357	486 107	482 768
<b>Cash flow for the period</b>	<b>-76 326</b>	<b>449 868</b>	<b>-30 019</b>	<b>469 628</b>	<b>203 970</b>
Liquid funds at beginning of period	354 236	159 946	311 419	139 993	159 946
Exchange rate difference in liquid funds	6 606	-1 440	3 116	-1 247	-9 680
<b>Liquid funds at end of period</b>	<b>284 516</b>	<b>608 374</b>	<b>284 516</b>	<b>608 374</b>	<b>354 236</b>

## Consolidated Change in Shareholders Equity

SEK Thousands	Attributable to Parent Company's shareholders				
	Share capital	Other paid in capital	Reserves	Retained earnings incl. profit for the year	Sum shareholders' equity
<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 - September 2020	-	-	-3 078	-24 160	-27 238
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	54	490 223	-	-	490 277
Share warrant program	-	1 331	-	-	1 331
<b>Shareholders' equity as of September 30, 2020</b>	<b>734</b>	<b>1 007 307</b>	<b>13 150</b>	<b>20 700</b>	<b>1 041 891</b>
Total comprehensive income October - December 2020	-	-	-13 333	-19 574	-32 907
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	-	-583	-	-	-583
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 - September 2021	-	-	6 877	-4 037	2 840
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	1	-	-	-	1
Share warrant program <sup>1)</sup>	-	1 239	-	-	1 239
<b>Shareholders' equity as of September 30, 2021</b>	<b>735</b>	<b>1 008 023</b>	<b>6 694</b>	<b>-2 911</b>	<b>1 012 541</b>

<sup>1)</sup> Cash payment for subscription in employees share warrant program, series 2021/2024.

## Condensed Consolidated Statement of Net Income per quarter

SEK Thousands	Jul-Sep 2021	Apr-Jun 2021	Jan-Mar 2021	Oct-Dec 2020	Jul-Sep 2020	Apr-Jun 2020	Jan-Mar 2020	Oct-Dec 2019
Net sales	54 935	59 263	58 325	60 277	42 736	30 393	46 455	62 416
Cost of goods sold	-17 000	-14 716	-15 645	-18 920	-9 602	-7 291	-11 073	-16 710
<b>Gross income</b>	<b>37 935</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>
Selling expenses	-23 344	-20 613	-19 696	-19 229	-13 470	-12 360	-14 840	-18 372
Administrative expenses	-9 053	-14 605	-11 033	-11 163	-8 462	-5 069	-5 648	-7 152
Research and development costs	-10 457	-14 034	-15 529	-15 886	-11 233	-12 186	-16 873	-17 964
Other operating revenues and expenses <sup>1)</sup>	888	-4 645	6 761	-9 406	-18 631	-6 196	2 002	-622
<b>Operating income</b>	<b>-4 031</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>
Financial income and expenses	2 956	-1 411	5 081	-11 610	-481	-6 047	6 550	-3 838
<b>Income after financial items</b>	<b>-1 075</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>
Taxes	-54	1 820	-2 231	6 363	4 457	2 738	-30	340
<b>Net income</b>	<b>-1 129</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>Attributable to</b>								
Parent Company's shareholders	-1 129	-8 941	6 033	-19 575	-14 685	-16 018	6 543	-1 902
Earnings per share, SEK	-0,04	-0,31	0,21	-0,68	-0,51	-0,60	0,25	-0,07
Earnings per share, SEK <sup>2)</sup>	-0,04	-0,31	0,20	-0,67	-0,51	-0,60	0,25	-0,07
Average number of outstanding shares	28 727 266	28 727 266	28 719 136	28 719 136	28 601 434	26 600 496	26 600 496	26 600 496
Average number of outstanding shares <sup>2)</sup>	29 101 266	29 101 266	29 444 136	29 327 136	28 975 434	26 600 496	26 600 496	26 879 496
Number of shares at closing day	28 752 397	28 752 397	28 719 136	28 719 136	28 719 136	26 600 496	26 600 496	26 600 496
Number of shares at closing day <sup>2)</sup>	29 126 397	29 126 397	29 444 136	29 444 136	29 093 136	26 600 496	26 600 496	26 879 496
<b>EBITDA (Operating income before depreciation and amortization)</b>	<b>4 181</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>
Depreciation and amortization on intangible assets	-5 278	-5 135	-5 470	-5 349	-4 114	-4 107	-4 115	-4 107
Depreciation and amortization on tangible assets	-2 934	-2 682	-2 554	-2 473	-3 318	-3 150	-3 412	-2 776
<b>Operating income</b>	<b>-4 031</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>

<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	Jul-Sep 2021	Apr-Jun 2021	Jan-Mar 2021	Oct-Dec 2020	Jul-Sep 2020	Apr-Jun 2020	Jan-Mar 2020	Oct-Dec 2019
<b>Net income</b>	<b>-1 129</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>Other comprehensive income</b>								
Items that may be reclassified to the income statement:								
Exchange rate differences	3 163	-3 704	7 418	-13 179	-3 654	-5 226	5 649	-3 691
Tax attributable to items that have been transferred, or can be transferred to net income	-	-	-	-153	299	319	-465	343
<b>Total other comprehensive income</b>	<b>3 163</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>Total comprehensive income</b>	<b>2 034</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>Attributable to</b>								
Parent Company's shareholders	2 034	-12 645	13 451	-32 907	-18 040	-20 925	11 727	-5 250

## Consolidated key ratios

SEK Thousands	January-September 2021	January-September 2020	July-September 2021	July-September 2020	January-December 2020
Gross margin non-Durable goods, %	75	79	73	78	77
Gross margin, %	73	77	69	78	74
EBITDA, %	8	-8	8	-26	-9
EBITDA (adjusted), %	12	11	10	22	11
Operating margin, %	-6	-26	-7	-44	-25
Net margin, %	-2	-20	-2	-34	-24
Equity/assets ratio, %	88	93	88	93	88
Income per share, SEK	-0,14	-0,91	-0,04	-0,51	-1,61
Shareholders' equity per share, SEK	35,22	36,28	35,22	36,28	35,11
Share price on closing day, SEK	387	272	387	272	314
Market cap on closing day, MSEK	11 113	7 797	11 113	7 797	9 018

## Condensed Income Statement, Parent Company

SEK Thousands	January-September 2021	January-September 2020	July-September 2021	July-September 2020	January-December 2020
Net sales	124 347	96 478	28 352	37 931	134 122
Cost of goods sold	-24 498	-25 031	-6 246	-11 274	-36 107
<b>Gross income</b>	<b>99 849</b>	<b>71 447</b>	<b>22 106</b>	<b>26 657</b>	<b>98 015</b>
Selling expenses	-34 760	-25 032	-13 560	-8 361	-36 675
Administrative expenses	-30 692	-17 955	-4 392	-7 485	-27 602
Research and development expenses	-33 871	-50 325	-9 923	-15 514	-65 268
Other operating revenues and expenses	1 116	-8 569	1 447	-7 208	-10 074
<b>Operating income</b>	<b>1 642</b>	<b>-30 434</b>	<b>-4 322</b>	<b>-11 911</b>	<b>-41 604</b>
Financial income and expenses	7 820	-153	3 467	-1 747	-10 609
<b>Income after financial items</b>	<b>9 462</b>	<b>-30 587</b>	<b>-855</b>	<b>-13 658</b>	<b>-52 213</b>
Year end dispositions	-	-	-	-	4 200
Taxes	-2 975	6 197	88	2 788	9 577
<b>Net income</b>	<b>6 487</b>	<b>-24 390</b>	<b>-767</b>	<b>-10 870</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 14,583 thousand (14,978), of which SEK 4,820 thousand (5,063) in the quarter.

## Condensed Balance Sheet, Parent Company

SEK Thousands	210930	200930	201231
<b>ASSETS</b>			
Intangible fixed assets	274 536	233 786	245 777
Property, plant and equipment	6 264	6 416	5 902
Financial assets	501 742	183 756	453 598
<b>Total non-current assets</b>	<b>782 542</b>	<b>423 958</b>	<b>705 277</b>
Inventories	19 074	22 846	16 561
Current receivables	20 739	30 596	25 602
Cash and bank	260 179	597 762	333 318
<b>Total current assets</b>	<b>299 992</b>	<b>651 204</b>	<b>375 481</b>
<b>Total assets</b>	<b>1 082 534</b>	<b>1 075 162</b>	<b>1 080 758</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
Shareholders' equity	1 008 544	1 015 427	1 000 817
Untaxed reserves	-	4 200	-
Provisions	1 454	1 310	1 311
Long-term non-interest-bearing liabilities	41 973	-	41 392
Short-term non-interest-bearing liabilities	30 563	54 225	37 238
<b>Total shareholders' equity and liabilities</b>	<b>1 082 534</b>	<b>1 075 162</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 334 million (655) and SEK 59 million (67) 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 42.0 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-September					
	Non-Durable goods		Durable goods		Total consolidated	
	2021	2020	2021	2020	2021	2020
Net sales	160 013	114 498	12 510	5 086	172 523	119 584
Cost of goods sold	-40 148	-23 837	-7 213	-4 129	-47 361	-27 966
<b>Gross income</b>	<b>119 865</b>	<b>90 661</b>	<b>5 297</b>	<b>957</b>	<b>125 162</b>	<b>91 618</b>
<b>Gross margin (%)</b>	<b>75</b>	<b>79</b>	<b>42</b>	<b>19</b>	<b>73</b>	<b>77</b>

SEK Thousands	July-September					
	Non-Durable goods		Durable goods		Total consolidated	
	2021	2020	2021	2020	2021	2020
Net sales	48 893	42 309	6 042	427	54 935	42 736
Cost of goods sold	-12 974	-9 422	-4 026	-180	-17 000	-9 602
<b>Gross income</b>	<b>35 919</b>	<b>32 887</b>	<b>2 016</b>	<b>247</b>	<b>37 935</b>	<b>33 134</b>
<b>Gross margin (%)</b>	<b>73</b>	<b>78</b>	<b>33</b>	<b>58</b>	<b>69</b>	<b>78</b>

## Note 4. Other operating revenue and expenses

SEK Thousands	Jul-Sep 2021	Apr-Jun 2021	Jan-Mar 2021	Oct-Dec 2020	Jul-Sep 2020	Apr-Jun 2020	Jan-Mar 2020	Oct-Dec 2019
Cost of cash-based incentive program for employees outside Sweden	-130	-3 860	7 084	-8 332	-12 469	-	2 541	237
Cost of reorganization	-	-	-	-	-5 375	-4 498	-	-
Other	1 018	-785	-323	-1 074	-786	-1 698	-539	-859
<b>Total</b>	<b>888</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>

# 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-September 2021	January-September 2020	July-September 2021	July-September 2020	January-December 2020
<b>Operating income</b>	<b>-10 198</b>	<b>-31 347</b>	<b>-4 031</b>	<b>-18 661</b>	<b>-45 675</b>
Depreciation and amortization on intangible assets	15 883	12 336	5 278	4 114	17 685
Depreciation and amortization on tangible assets	8 170	9 880	2 934	3 318	12 353
<b>EBITDA (Operating income before depreciation and amortization)</b>	<b>13 855</b>	<b>-9 131</b>	<b>4 181</b>	<b>-11 229</b>	<b>-15 637</b>

## Gross margin

SEK Thousands	January-September 2021	January-September 2020	July-September 2021	July-September 2020	January-December 2020
Operating income					
Net sales	172 523	119 584	54 935	42 736	179 861
Operating expenses					
Cost of goods sold	-47 361	-27 966	-17 000	-9 602	-46 886
<b>Gross income</b>	<b>125 162</b>	<b>91 618</b>	<b>37 935</b>	<b>33 134</b>	<b>132 975</b>
<b>Gross margin %</b>	<b>73</b>	<b>77</b>	<b>69</b>	<b>78</b>	<b>74</b>

## Gross margin non-durable goods

SEK Thousands	January-September 2021	January-September 2020	July-September 2021	July-September 2020	January-December 2020
Operating income					
Net sales of non-Durable goods	160 013	114 498	48 893	42 309	169 425
Operating expenses					
Cost of non-Durable goods sold	-40 148	-23 837	-12 974	-9 422	-38 980
<b>Gross income, non-Durable goods</b>	<b>119 865</b>	<b>90 661</b>	<b>35 919</b>	<b>32 887</b>	<b>130 445</b>
<b>Gross margin, non-Durable goods %</b>	<b>75</b>	<b>79</b>	<b>73</b>	<b>78</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	210930	200930	201231
Shareholders' equity	1 012 541	1 041 891	1 008 461
Total assets	1 144 377	1 119 096	1 150 309
<b>Equity/assets ratio %</b>	<b>88</b>	<b>93</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>Adjusted EBITDA-margin, %</b>	EBITDA (operating income before depreciation and amortization) adjusted for items affecting comparability, 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. Furthermore, the Company believes that adjusted EBITDA gives a fairer picture of the Company's EBITDA for the core business.
<b>Adjusted EBIT-margin, %</b>	EBIT (operating income), adjusted for items affecting comparability, 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. Furthermore, the Company believes that adjusted EBIT gives a fairer picture of the Company's EBIT for the core business.
<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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