Report on Operations 2021

XVIVO Perfusion AB (publ)



XVIVO

Q4 2021

Fourth quarter 2021 (October 1 - December 31)

• Net sales amounted to SEK 85.9 million (60.3), corresponding to an increase of 42 percent in SEK and 42 percent in local currencies.

Report on Operations 2021

- Net sales of non-durable goods amounted to SEK 74.0 million (54.9), corresponding to an increase of 35 percent in SEK and 34 percent in local currencies.
- Organic growth amounted to 32 percent in local currencies.
- Machine perfusion accounted for 55 percent (56) of net sales.
- Operating profit before depreciation and amortization (EBITDA) amounted to SEK- 0.1 million (-6.5), corresponding to an EBITDA margin of 0 percent (-11). Adjusted EBITDA amounted to SEK 9.6 million (6.8), corresponding to an adjusted EBITDA margin of 11 percent (11).
- Operating profit (EBIT) amounted to SEK -8.3 million (-14.3). Adjusted EBIT amounted to SEK 1.4 million (-1.0).
- Net profit amounted to SEK 12.2 million (-19.6). Earnings per share amounted to SEK 0.42 (-0.68).
- Cash flow from operating activities amounted to SEK -0.6 million (-22.0). Total cash flow amounted to SEK 111.2 million (-245.9), primarily a net of proceeds from directed new share issue and the purchase price paid for acquisition and investments in R&D projects.
- Cash and cash equivalents at the end of the quarter amounted to SEK 398.7 million (354.2).

Significant events during the quarter

- XVIVO acquired 100 percent of the shares in the US organ recovery company Star Teams. The acquisition took place at a purchase price of up to USD 26.1 million with an initial purchase price of USD 12.3 million and an additional potential earn-out of up to USD 13.8 million.
- The acquisition of STAR Teams was financed by a new share issue whereby the company raised SEK 250 million before transaction costs. In addition to strong support from existing shareholders, several new Swedish and international institutional investors participated.
- With XVIVO's heart preservation technology a donor heart could be kept alive for 7 hours and 18 minutes before being successfully transplanted. This means a record when using XVIVO's technology in a clinical trial and was achieved by an Australian clinic.
- XVIVO is accelerating the business operations in Brazil, the world's third largest organ transplantation market, by signing a partnership contract with Contatti Medical, market leader on Brazil's organ transplantation market.
- The North American organization has been strengthened further by the appointment of Fredrik Dalborg as Managing Director North America, and by the appointment of Jaya Tiwari as VP of Clinical and Regulatory Affairs for the US. Also, a new office was opened in Philadelphia.

The period (January 1 - December 31)

- Net sales amounted to SEK 258.4 million (179.9), corresponding to an increase of 44 percent in SEK and 50 percent in local currencies.
- Net sales of non-durable goods amounted to SEK 234.0 million (169.4), corresponding to an increase of 38 percent in SEK and 45 percent in local currencies.
- Organic growth amounted to 27 percent in local currencies.
- Machine perfusion accounted for 53 percent (43) of net sales.
- Operating profit before depreciation and amortization (EBITDA) amounted to SEK 13.8 million (-15.6), corresponding to an EBITDA margin of 5 percent (-9). Adjusted EBITDA amounted to SEK 29.5 million (20.2), corresponding to an adjusted EBITDA margin of 11 percent (11).
- Operating profit (EBIT) amounted to SEK -18.5 million (-45.7). Adjusted EBIT amounted to SEK -2.7 million (-9.9).
- Net profit amounted to SEK 8.2 million (-43.7). Earnings per share amounted to SEK 0.28 (-1.61).
- Cash flow from operating activities amounted to SEK -12.1 million (-12.3). Total cash flow amounted to SEK 34.8 million (204.0), primarily a net of the proceeds from directed new share issue and the purchase price paid for acquisition and investments R&D projects.
- Cash and cash equivalents at the end of the period amounted to SEK 398.7 million (354.2).

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.
- Guidelines from NICE supporting EVLP as the standard lung preservation procedure were issued in the UK.
- 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.
- A pilot project in advanced data analysis from liver perfusion was initiated with UMC Groningen as a partner.

Events after the reporting period

- On January 7, 2022, XVIVO's innovative technology for heart preservation was used in the world's first ever successful pig to human heart xenotransplantation. A team at the University of Maryland School of Medicine, USA, performed the procedure.
- On January 21, 2022, XVIVO obtained 510(k) approval by the FDA for marketing and sales of the product Kidney Assist Transport on the US market. The product is a transport device for kidney and the features of the technology were highlighted in the scientific journal The Lancet in November 2020.
- The Board proposes no dividend to be paid for the 2021 financial year and retained earnings to be carried forward.

Key ratios

	January-December	January Docombor	October-December	October-December
TSEK	2021	2020	2021	2020
Net sales	258 386	179 861	85 863	60 277
Non-Durable goods	233 971	169 425	73 958	54 927
Durable goods	18 365	10 436	5 855	5 350
Services ²⁾	6 050	-	6 050	-
Machine perfusion share of net sales, %	53	43	55	56
Gross margin, %	73	74	73	69
Non-Durable goods	76	77	77	72
Durable goods	43	24	44	29
Services	53	-	53	-
EBIT	-18 498	-45 675	-8 300	-14 328
EBIT (adjusted) ¹⁾	-2 716	-9 866	1 361	-1 050
EBITDA	13 759	-15 637	-96	-6 506
EBITDA (adjusted) ¹⁾	29 541	20 172	9 565	6 772
Earnings per share, SEK	0,28	-1,61	0,42	-0,68
Cash flow from operating activities	-12 059	-12 266	-562	-21 999
Changes in net sales				
Organic growth in local currency, %	27	-24	32	-25
Acquired growth, %	22	7	10	27
Currency effect, %	-5	-2	-	-5
Total growth, %	44	-19	42	-3

¹⁾ Adjusted for effect from cost provision attributable to cash-based incentive program for employees outside of Sweden, integration costs and cost relating to acquisition process. Net adjustment totals SEK 9.7 (13.2) million for the quarter. Net adjustment for the period totals SEK 15.8 (35.8) million.

 $^{\rm 2)} {\rm Services}$ refers to revenue from the acquired entity STAR Teams Inc.

CEO comment

Year ends on strong quarter

XVIVO's strong conclusion to 2021 generates positive prospects for the coming year. Fourth-quarter sales were solid and new sales records were set in all business areas. XVIVO acquired the groundbreaking organ recovery company STAR Teams in the quarter, a strategically significant acquisition on the key US market. The integration came off to an enthusiastic start and STAR Teams returned strong growth in the fourth quarter.



Dag Andersson, CEO

"It was particularly
 pleasing that revenue
 from machine perfusion
 increased as activity
 intensified or restarted in
 several EVLP programs in
 clinics across the US and
 Europe."

Total sales amounted to SEK 86 million (60) in the fourth quarter, with organic growth of 32 percent. XVIVO made a strong recovery compared to the third quarter when sales were affected by the impact of the Delta virus on global healthcare. We expect the number of transplants to increase gradually across all markets as the effect of the pandemic on healthcare operations decreases.

Thoracic's sales amounted to SEK 59 million (44) with organic growth of 33 percent. It was particularly pleasing that revenue from machine perfusion increased as activity intensified or restarted in several EVLP programs in clinics across the US and Europe. This means that we are starting the new year with good prospects of increased activity in the clinics that use XVIVO's technology around the world.

The business area Abdominal also returned a strong quarter. Sales totaled SEK 21 million (17) with organic growth of 29 percent. Sales were almost exclusively derived from Europe where we are continuing to increase our installed base of perfusion machines. Sales of durable goods totaled SEK 6 million (3), a record quarter.

STAR Teams, comprising the new business area Services, provided SEK 6 million (-) in sales for the period November-December. In December, the company reached a milestone of 400 organ recoveries in a single year – double the figure for 2020. STAR Teams is a pioneer in its field and adds considerable value to transplant clinics in the US through its service offering.

Gross margin also increased in the fourth quarter. Thoracic's gross margin excluding durable goods was 83 percent (80) in the quarter and amounted to 55 percent (50) for Abdominal. The margin improvements were mainly due to higher prices to customers and economies of scale from increased sales.

We launched initiatives aimed at further strengthening our focus on the important North American market in the fourth quarter. We recruited a Head of North America and increased the representation of US-based members in XVIVO's management. We also opened a new office in Philadelphia, which will act as a hub in the integration of STAR Teams.

Our development projects are continuing, and the final clinics are now being included in the European Heart study and the PrimECC study. In the investigator-initiated heart trials in Australia/New Zeeland a donor heart was preserved outside the body for seven hours and 18 minutes before being successfully transplanted. That is significantly longer than what is normally possible and a record for XVIVO's groundbreaking heart technology when used in clinical trials.

The pandemic continues to put public healthcare services under pressure. The impact on transplant activity around the world varied in 2021, both in terms of organ type and market. However, the overall transplant trend looks positive. In 2021, historic 40,000 successful organ transplants were completed on XVIVO's main market in the US. Compared to the previous year, transplants increased for all organ types with the exception of lung.

To conclude, I would like to highlight two news items communicated in January 2022. The world's first successful xenotransplant of a heart from pig to human was carried out by a transplant team at the University of Maryland School of Medicine in the US. XVIVO's innovative heart technology was a key factor in the transplant's success.

In January, XVIVO obtained 510(k) approval from the FDA for Kidney Assist Transport for sales in the US, the world's largest kidney market. In 2021, close to 15,000 kidney transplants from deceased donors were carried out in the US. The FDA approval is good news and will generate new business opportunities for us in 2022!

Dag Andersson, CEO

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.



Strategic drivers

CUSTOMER-DRIVEN

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-December 2021	January-December 2020	October-December 2021	October-December 2020
Net Sales non-Durable Goods	233 971	169 425	73 958	54 927
Net Sales Durable Goods	18 365	10 436	5 855	5 350
Net Sales Services	6 050	-	6 050	-
Net Sales Total	258 386	179 861	85 863	60 277
Cost of Goods non-Durable Goods	-56 923	-38 980	-16 775	-15 143
Cost of Goods Durable goods	-10 493	-7 906	-3 280	-3 777
Cost of Sales Services	-2 849	-	-2 849	-
Cost of Goods Total	-70 265	-46 886	-22 904	-18 920
Gross income non-Durable Goods	177 048	130 445	57 183	39 784
Gross margin non-Durable Goods, %	76%	77%	77%	72%
Gross income Durable Goods	7 872	2 530	2 575	1 573
Gross margin Durable Goods, %	43%	24%	44%	29%
Gross income Services	3 201	-	3 201	-
Gross margin Services, %	53%	0%	53%	0%
Gross income Total	188 121	132 975	62 959	41 357
Gross margin Total, %	73%	74%	73%	69%
Selling expenses	-99 290	-59 899	-35 637	-19 229
Administrative expenses	-55 802	-30 342	-21 111	-11 163
Research and development expenses	-55 594	-56 178	-15 574	-15 886
Other operating revenues and expenses ¹⁾	4 067	-32 231	1 063	-9 406
Operating Income	-18 498	-45 675	-8 300	-14 328
Amortization and depreciation cost of goods sold	922	462	663	-180
Depreciation administrative expenses	3 328	3 154	786	754
Amortization of research and development expenses	23 085	21 133	5 630	6 070
Depreciation other operative expenses	4 922	5 289	1 125	1 178
EBITDA (Operating income before depreciation and amortization)	13 759	-15 637	-96	-6 506
EBITDA, %	5%	-9%	0%	-11%
EBITDA (adjusted) ²⁾	29 541	20 172	9 565	6 772
EBITDA (adjusted), %	11%	11%	11%	11%

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

²⁾Adjusted for effect from cost provision attributable to cash-based incentive program for employees outside of Sweden, integration costs and cost relating to acquisition process. Net adjustment totals SEK 9.7 (13.2) million for the quarter. Net adjustment for the period totals SEK 15.8 (35.8) million.

Summary

The quarter October - December 2021

Net sales and income

The fourth quarter resulted in a strong recovery in sales compared to the third quarter, especially within machine perfusion where XVIVO could see increased activity in both Thoracic and Abdominal. The recovery was broad across most markets. Organic growth amounted to 32 percent in local currencies.

Net sales during the quarter increased by 42 percent and amounted to SEK 85.9 million (60.3). This represents an increase of 42 percent also in local currencies. Net sales without durable goods increased by 35 percent and amounted to SEK 74.0 million (54.9). The increase corresponds to 34 percent in local currencies

Machine perfusion accounted for 55 percent (56) of net sales. Static preservation and other sales (revenue from service and training, etc.) accounted for the remaining part of the sales.

Gross margin for the quarter was 73 percent (69) and gross margin without durable goods was 77 percent (72). For comments on margins, see each business area (page 12-13).

Operating profit before depreciation and amortization (EBITDA) amounted to SEK -0.1 million (-6.5) corresponding to an EBITDA margin of 0 percent (-11). EBITDA was positively affected by the resolution of the provision for cash-based incentive programs for employees outside Sweden of SEK 0.8 million and charged with acquisition costs of SEK -10.0 million and integration costs of SEK -0.5 million. Adjusted for these items totaling net SEK-9.7 million (-13.2), EBITDA amounted to SEK 9.6 million (6.8), corresponding to an adjusted EBITDA margin of 11 percent (11).

Operating profit (EBIT) amounted to SEK -8.3 million (-14.3). EBIT adjusted for the above-mentioned specific costs, amounted to SEK 1.4 million (-1.0).

Selling expenses in relation to sales amounted to 42 percent (32) for the quarter. The increased selling expenses for the quarter include investments in marketing projects and non-recurring items of about SEK 4,0 million. R&D costs amounted to 18 percent (26) of net sales. Administration costs amounted to 25 percent (19) of net sales. The increase in administration costs include acquisition costs of SEK 10.0 million.

Other operating income and operating expenses amounted to SEK 1.1 million (-9.4) during the quarter. The item consists primarily of positive effects from the cash-based incentive program for employees abroad as well as currency exchange effects. See Note 4 for more information.

Financial income and expenses for the quarter amounted to SEK 18.5 million (-11.6), primarily due to a positive effect from the resolution of a cost provision of EUR 2 million attributable to a part of the earn-out linked to the acquisition of XVIVO B.V. (former Organ Assist), which will not fall out for payment. The remaining part of the earn-out consideration, EUR 2 million, will be paid during the first quarter of 2022.

During the quarter, SEK 28.5 million (18.9) of development expenditures were capitalized as intangible assets. Development expenditures are primarily expenditures within 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 (5.1) during the quarter, of which SEK 3.9 million (3.9) is attributed to regulatory approvals for the company's products withing lung transplantation. The remaining part relates to amortization of R&D projects within the abdominal operations.

Cash flow

Cash flow from operating activities for the quarter amounted to SEK -0.6 million (-22.0) and was affected by acquisition costs and an increase in accounts receivable, partly because of the inclusion of STAR Teams. Cash flow from investment activities amounted to SEK -125.2 million (-222.2) and is explained by the paid initial purchase price for STAR Teams of net SEK -93.2 million. Furthermore, SEK -28.8 million (-19.7) was invested in intangible assets and SEK -3.1 million (-0.8) was invested in tangible assets. Cash flow from financing activities amounted to SEK 250 million minus issue costs of SEK 5.9 million. Exchange differences in cash and cash equivalents positively impacted cash flow for the quarter by SEK 3.0 million (-8.2). Cash and cash equivalents at the end of the quarter amounted to SEK 398.7 million (354.2).

Net sales per segment (R12)





Net sales per product category (R12)





EBITDA och EBITDA-margin (adjusted, R12)



Significant events during the quarter

XVIVO acquired the US organ recovery company Star Teams.

On October 28, XVIVO acquired 100 percent of the shares and votes in the US organ recovery company Star Teams Inc. ("Star Teams") for an initial purchase price of USD 12.5 million with an additional potential earn-out payment of up to USD 13.8 million, paid out earliest in 2024. Star Teams delivers an integrated data-driven approach to organ recovery in which the company's surgeons are on call 24/7, 365 days per year, to retrieve organs and deliver them safely to transplant centers around the US with a mission to save lives. Through the acquisition, XVIVO extends its product portfolio with value-added services within the organ transplantation industry, becoming a transplant powerhouse as the most comprehensive turnkey provider for transplant centers, driving the adoption of machine perfusion. The transaction was completed on November 9, 2021 and STAR Teams was included in the Group's financial reporting for the period November-December.

Directed new share issue raised SEK 250 million.

The acquisition of STAR Teams was financed through a new share issue on October 28, through an accelerated book-building procedure. 746,269 shares were issued at a subscription price of SEK 335 per share, through which the Company recieved SEK 250 million before issue costs. Issue costs totaled SEK 6 million. In addition to strong support from existing shareholders, several new Swedish and international institutional investors participated in the directed issue. The directed issue entailed a dilution of approximately 2.5 percent of the shares and votes in the Company.

Change in number of shares and votes

The directed new share issue increased the number of shares and votes in XVIVO Perfusion AB (publ) by 746,269 shares and there were 29,498,666 shares in the company as of December 31, 2021. Share capital increased by SEK 19,074 and totaled SEK 753,949 as of December 31, 2021.

New record for preserving donor heart outside the body using XVIVO technology

XVIVO is setting new standards in heart transplantation. In an ongoing clinical trial in Australia and New Zealand, a donor heart was preserved using XVIVO's Non Ischemic Heart Preservation technology for 7 hours and 18 minutes before successful transplantation into a 55-year-old man. The study investigates whether the new preservation technology can safely extend the transport period for donated hearts beyond the current 4 hour limit. By pushing the ideal time limit from less than 4 hours for traditional storage using ice to more than 7 hours using XVIVO's technology, more lives will be saved. The first patients in the trial were included in the first quarter 2021.

XVIVO accelerates operations in Brazil through partnership with Contatti Medical

By selling and distributing its products through Contatti Medical's well-established network in Brazil, XVIVO's market access will increase significantly. Contatti Medical is the current market leader in its segment in Brazil. The country is currently the world's third largest abdominal organ transplantation market and strategically important for XVIVO. Every year more than 6,000 kidney transplants are carried out in Brazil, and more than 2,000 liver transplants. Currently, XVIVO has systems for machine perfusion of kidney and liver, the products Kidney Assist and Liver Assist. marketed and sold on the Brazilian market.

Strengthened organization and increased focus on North America

The organization in North America was strengthened by the appointment of Fredrik Dalborg as Managing Director North America and the appointment of Jaya Tiwari as Vice President Clinical and Regulatory Affairs. XVIVO opened a new office in Philadelphia in the US, which will act as a hub in the integration of STAR Teams and form the basis of XVIVO's commercial operations in North America. The office in Denver, USA, will remain the company's competence center for development of innovative lung technology.

The period January - December 2021

Net sales and income

For the full year 2021, we can conclude that the Covid-19 pandemic has continued to have a major impact on transplant activity globally. Available healthcare resources have largely focused on Covid-19 and more patients than ever are now waiting for a new organ.

Transplant activity varied in 2021 depending on organ and region. In XVIVO's main market, the US, the number of transplants for all organs except lung actually increased compared to both 2019 and 2020. For example, lung transplants in the US were 7 percent lower in 2021 compared to 2019. In Europe, the rate of recovery has varied by country and organ. However, the total number of transplants in Europe during 2021 has not recovered to 2019 levels.

Net sales increased by 44 percent during the period and amounted to SEK 258.4 million (179.9). This represents an increase of 50 percent in local currencies. Net sales of non-durable goods increased by 38 percent and amounted to SEK 234.0 million (169.4). The increase corresponds to 45 percent in local currencies.

Organic growth amounted to 27 percent in local currencies.

Machine perfusion accounted for 53 percent (43) of net sales. Static preservation and other sales (revenue from service and training, etc.) accounted for the remaining part of the sales.

Gross margin for the period was 73 percent (74) and gross margin without durable goods was 76 percent (77). For comments on margins, see business area information on page 12-13.

Operating profit before depreciation and amortization (EBITDA) amounted to SEK 13.8 million (-15.6), corresponding to an EBITDA margin of 5 percent (-9). EBITDA was positively affected by the resolution of a provision for the cash-based incentive program for employees outside Sweden of SEK 3.9 million and has been charged with M&A costs of SEK -13.3 million and integration costs of SEK -6.3 million. Adjusted for these items with a net of SEK -15.8 million (-35.8), EBITDA amounted to SEK 29.5 million (20.2), corresponding to an adjusted EBITDA margin of 11 percent (11).

Operating income (EBIT) amounted to SEK -18.5 million (-45.7). EBIT adjusted for the above-mentioned items amounted to SEK -2.7 million (-9.9).

Selling expenses as a proportion of sales amounted to 38 percent (33) in the period. The increased selling expenses include investments in organization and marketing projects, but also integration costs of SEK 2.8 million and non-recurring items of about SEK 4.0 million. R&D expenses amounted to 22 percent (31) of sales. Administrative expenses amounted to 22 percent (17) of sales. The increase in administration costs include acquisition costs of SEK 1.3.3 million and integration costs of SEK 3.6 million. The company received US government support totaling SEK 3.8 million, which has been recognized as reduced personnel expenses mainly within commercial and R&D functions.

Other operating income and operating expenses amounted to SEK 4.1 million (-32.2) in the period. The item primarily consists of positive effects from the resolution of provision for cash-based incentive program for employees abroad of SEK 3.9 million. The remainder primarily consists of currency conversion effects. See Note 4 for more information.

Financial income and expenses for the period amounted to SEK 25.2 million (-11.6), primarily due to a positive effect from the resolution of a cost provision of EUR 2 million attributable to a part of the earn-out linked to the acquisition of XVIVO B.V. (former Organ Assist), which will not to fall out for payment. The remaining part of the earn-out consideration, EUR 2 million, will be paid during the first quarter of 2022.

During the period, SEK 81.0 million (60.5) of development expenditure were capitalized as intangible assets. Development expenditure essentially relate to R&D expenses in connection with obtaining regulatory approvals in the US and Europe. Amortization of capitalized development expenses amounted to SEK 20.0 million (16.7) in the period, of which SEK 15.5 million (15.5) was attributed to regulatory approvals for the company's products in lung transplantation. The remainder relates to amortization of R&D projects in the Abdominal business area.

Cash flow

Cash flow from operating activities in the period amounted to SEK -12.1 million (-12.3). Changes in working capital affected cash flow by SEK-23.2 million, driven by capital tied-up in inventories to meet future customer demand and product launches, but also driven by increased accounts receivables, partly due to the inclusion of STAR Teams. One-time items such as M&A costs and payment of cash-based incentive programs for foreign employees have also affected the cash flow for the period.

Net sales

SEK 258 million

Gross margin

73%

Adjusted EBITDA



Cash flow from investment activities amounted to SEK-187.7 million (-266.5), of which SEK -83.9 million (62.0) was invested in intangible assets and SEK -10.2 million (-2.6) was invested in tangible assets. Investment activities also include the acquisition of STAR Teams with SEK -93.2 million. Cash flow from financing activities amounted to SEK 234.6 million (482.8), primarily explained by proceeds from directed share issue of SEK 250 million, minus issue costs of SEK 5.9 million. Exchange rate differences in the period had a positive cash flow effect of SEK 9.6 million (-9.7). Cash and cash equivalents at the end of the period amounted to SEK 398.7 million (354.2).

Financing

XVIVOs operations shall be conducted with a sustainable and efficient capital structure. The company's equity ratio is strong and amounted to 83 percent (88) 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

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 highest prioritized 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.

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 followup 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 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, Liver Assist, is CE-marked and at present primarily sold in Europe, but also through distributors on other, smaller markets.

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 company's strategic focus areas for 2022-2026 were presented. 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.

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.

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 2019/2021.

Through the directed new share issue carried out in the fourth quarter, the number of shares and votes in XVIVO Perfusion AB (publ) increased by 746,269 shares in the quarter, and there were 29,498,666 shares in the company as of December 31, 2021. Share capital increased by SEK 19,074 and totaled SEK 753,949 as of December 31, 2021.

Significant events after the end of the period

XVIVO's innovative technology for heart preservation was used in the world's first successful xenotransplant (pig to human)

On January 7, 2022, the world's first ever successful pig to human heart transplant took place, a groundbreaking milestone in the field of transplantation. A team at the University of Maryland School of Medicine, USA, performed the procedure. The recipient was a 57-year-old terminally ill man who received a heart from a genetically modified pig. After retrieval, the pig heart was preserved using XVIVO's heart perfusion device and proprietary solution until transplanted.

Xenotransplantation, transplantation between species, presents a potential solution to the critical organ shortage. Groundbreaking research using XVIVOs heart preservation technology has achieved long-term survival after xenotransplants of hearts from genetically modified pigs to primates in recent years. Based on this extensive research, the first ever transplant of a heart from a genetically modified pig to a human has now taken place.

510(k) approval for Kidney Assist Transport received from the FDA in the US

On January 21, 2022, XVIVO obtained regulatory approval (510(k) by the FDA for the marketing and sale of the product Kidney Assist Transport on the US market.

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. The technology was highlighted in scientific journal The Lancet in November 2020.

Following the announcement of XVIVO's acquisition of XVIVO B.V. (former Organ Assist) on October 1, 2020, the launch of Kidney Assist Transport has been an important milestone in XVIVO's strategy of establishing a commercial presence in abdominal transplantation in the US. This is the largest market by some margin, with approximately 18,700 kidney transplants from deceased donors in 2021.

Business area development

XVIVO's operations are conducted in three business areas: Thoracic (lung and heart transplantation), Abdominal (liver and kidney transplantation) and Services (Organ recovery). Within each business area commercial and R&D activities take place.

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 xenotransplantation.

Summary

SEK Thousands	January- December 2021	January- December 2020	October- December 2021	October- December 2020
Net sales	198 628	163 292	59 227	43 708
Non-Durable goods	192 063	155 572	58 929	41 074
Durable goods	6 565	7 720	298	2 634
Gross margin, %	79	77	82	76
Non-Durable goods	81	79	83	80
Durable goods	30	19	7	18

The quarter October - December 2021

Net sales during the quarter increased by 36 percent compared to the previous year and amounted to SEK 59.2 million (43.7). In local currencies, this represented a growth of 33 percent. Net sales of non-durable goods increased by 44 percent and amounted to SEK 58.9 million (41.1). The good sales performance in the fourth quarter was driven by a strong recovery in North America and Europe, mainly within machine perfusion (EVLP), where the company's revenue increased by 85 percent compared to the third quarter.

Organic growth amounted to 33 percent in local currencies.

Machine perfusion accounted for 44 percent (40) of net sales. Static preservation and other sales accounted for the remaining part of net sales. In December, an XPS machine was placed in a clinic in Berlin, Germany.

Gross margin for the quarter was 82 percent (76). Gross margin without durable goods amounted to 83 percent (80). The margin improvement was mainly driven by economies of scale from increased sales and price increases in the US market.

The period January - December 2021

Net sales increased in the period compared to the corresponding period in the previous year, amounting to SEK 198.6 million (163.3). In local currencies, this represented a growth of 27 percent. Net sales of non-durable goods increased by 23 percent, amounting to SEK 192.1 million (155.6). In local currencies, this represented a growth of 29 percent.

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

 $Organic \ growth \ amounted \ to \ 27 \ percent \ in \ local \ currencies.$

Two XPS machines were sold during the period, both in the United States, and one XPS machine was placed in Berlin, Germany.

Gross margin for the period was 79 percent (77). Gross margin excluding durable goods was to 81 percent (79).

Net sales per business area (R12)



Net sales per product category, Thoracic (Q4)



Machine perfusion, 44%
Static preservation, 53%
Other, 3%

Abdominal

The Abdominal business area consists of XVIVO's business within liver and kidney transplantation. XVIVO offers machine perfusion products for both organs. In 2021, the products were primarily sold in selective markets in Europe at present, but also on smaller markets outside North America. In January 2022, XVIVO received regulatory approval to sell Kidney Assist Transport in the US.

Summary

SEK Thousands	January- December 2021	January- December 2020	October- December 2021	October- December 2020
Net sales	53 708	16 569	20 586	16 569
Non-Durable goods	41 908	13 853	15 029	13 853
Durable goods	11 800	2 716	5 557	2 716
Gross margin, %	52	48	54	48
Non-Durable goods	53	50	55	50
Durable goods	50	41	50	41

The quarter October – December 2021

Net sales during the quarter amounted to SEK 20.6 million (16.6), an increase of 24 percent compared to the previous year. The increase was 29 percent in local currencies. Revenues were generated mainly in Europe and consisted to 80 percent of revenues from liver transplantation. Sales of durable goods amounted to SEK 5.6 million (2.7), which is a record for one quarter, mainly due to a strong quarter for installations of Liver Assist machines.

Organic growth was 29 percent in local currencies.

Gross margin without durable goods amounted to 55 percent (50) during the quarter, partly strengthened by oneoff factors. Underlying gross margin on sales was in line with the third quarter.

The period January - December 2021

Net sales during the period amounted to SEK 53.7 million (16.6. Since XVIVO's abdominal business was acquired in the fourth quarter of 2020, comparison figures for the Group for the period January – September 2021 are missing. However, the underlying business showed an organic growth for the full year of 35 percent in local currencies.

Gross margin without durable goods in the period was 53 percent (50). Price increases were carried out in the first quarter of the year according to plan, but the positive effect on gross margin was partly absorbed, temporarily, by increased purchase prices. A supplier change has been performed and the gross margin is expected to be strengthened after regulatory approvals and certifications as the new products have a lower cost of production.

Services

Business area Services consists of STAR Team's thoracic organ recovery business. Organ recovery refers to organ removal from the donor body, preservation of organs in cold solutions during transport and logistics and coordination before and during organ recovery. STAR Teams, established 2019, is a pioneer in the US market and provides its services to about ten to fifteen US clinics.

Summary

	January- December	January- December	October- December	October- December
SEK Thousands	2021	2020	2021	2020
Net sales	6 050	-	6 050	-
Gross margin, %	53	-	53	-

STAR Teams doubled the number of organs recovered in 2021 compared to 2020. The growth came from a gradually increased customer base during the year. The company was acquired on 9 November and is included in the XVIVO Group's accounts during the period November-December. The gross margin in 2021 primarily includes costs for surgical teams and the margin has been reduced to some extent due to investments in the workforce during the year. The margin is expected to increase gradually as new customers are added and as economies of scale are achieved.

Net sales per product category, Abdominal (Q4)



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

Organs recovered 2021



R&D Portfolio

Development projects

Project	Description	Status
Heart transplantation	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.	XVIVO has a program of multicenter clinical studies that will form the basis for the application for regulatory approval of the products in all major markets in the world. In Europe, nine clinics now actively include patients in XVIVO's study. Four more clinics are in the start-up phase. In 2021, all activated clinics have been trained and prepared. The initial experience of the users of the technology has been positive. A similar multicenter study is also in the planning phase in the US, where the company has received a breakthrough device designation. Discussions about the design of the study are ongoing with the FDA. In addition to the studies conducted by XVIVO, research- initiated studies with XVIVO's technology are ongoing in Lund and Australia. The latter has reported successful transplants after transport times of donated hearts longer than a full 7 hours using XVIVO technology.
Kidney transplantation	As for other organs, there is a shortage of transplantable kidneys. Studies have demonstrated that transport of kidneys with ongoing perfusion improves post-transplant outcomes.	An international study of high quality published in The Lancet 2020 shows benefits for the recipient when the kidney is transported perfused with an oxygenated solution. This is the technology unique to XVIVO. The combination of new perfusion technology and solutions will be the focus of future research in the field of organ.
Liver transplantation	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.	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. Further investigator-driven studies using XVIVO's technology are ongoing. The combination of new perfusion technology and optimized solutions will be the focus of future research in the field.
PrimECC®	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 [®] .	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 are available. The study is ongoing in Sweden. Planning underway for the start of study in Denmark, Norway and Germany during the first part of 2022

Research projects

Project	Description	Status
Xeno-transplantation	Xenotransplantation involves the use of non-human organs in transplantation. The method is currently at the research stage for several organs.	The first successful human transplant took place in January 2022 and was followed by great media coverage. XVIVO will continue to support ground-breaking research in the field and our technology to preserve the function of the heart is currently used by two world leading research groups.

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 2021 which, alongside the Code of Conduct, is available at www.xvivogroup.com.

Organization and staff

XVIVO employs 113 people, of which 51 women and 62 men. Of these, 46 people are employed in Sweden and 67 outside Sweden. The head office is located in Gothenburg, Sweden and our subsidiaries are located in Lund, Sweden, Denver and Philadelphia, 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 XVVO's regular quality system.

The market risks that are deemed to have a particular impact on XVVO'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 <u>www.xvivogroup.com</u>.

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.

Annual General Meeting and Annual Report

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on April 26, 2022 in Gothenburg. Shareholders who wish to have a matter dealt with at the meeting may request this in writing from the Board of Directors. Such request for consideration of the matter is sent to XVIVO Perfusion AB (publ), Att: Chairman of the Board, Box 53015, SE-40014 Gothenburg and must be submitted to the Board of Directors no later than seven weeks before the meeting, or at least in time so that the matter, if necessary, can be included in the notice convening the meeting.

XVIVO Perfusion's Annual Report for 2021 is expected to be available for download on XVIVO Perfusion's website during week 14.

Dividend

The Board proposes no dividend to be paid for the 2021 financial year and retained earnings to be carried forward.

Outlook

The extent to which the Covid-19 pandemic will affect XVIVO's sales and clinical trials in 2022 remains largely dependent on how the pandemic affects intensive care operations on our main markets in the US and Europe, and on how hospitals prioritize their transplantation programs. There is a clear ambition to sharply increase the number of transplants on markets such as the US, and therefore we assess that transplantation activity will be prioritized. Transplantation is a life-saving treatment with long waiting lists. Accordingly, XVIVO assesses that the number of transplants, and thereby demand for XVIVO's products will continue to increase.

In 2022, XVIVO will continue to focus sharply on regulatory applications, clinical studies and product development in all major organ areas. In heart transplantation, the goal is to accelerate inclusion of patients in the clinical multi-center studies in Europe and Australia. The goal is also to start the clinical heart trial in the US towards the summer. The PrimECC[®] study is expected to accelerate as more clinics are now being included. For Liver Assist, the initial objective is to make a decision regarding the regulatory way forward in the US, in consultation with the FDA.

Significant events after the reporting period

In January 2022, two very positive events occurred in that the first successful xenotransplantation of heart from pig to human was performed using XVIVO's heart technology, and that XVIVO received regulatory approval in the US for sale of the product Kidney Assist Transport. These events are further described on page 11. No other events occurred after the end of the reporting period that affect the assessment of the financial information in this report.

The Board of Directors and the CEO declare that the year-end report provides a true and fair view of the Group's and the Parent Company's operations, position and results and describes the significant risks and uncertainties faced by the Parent Company and the companies that are part of the Group.

Gothenburg, 27 January 2022

Gösta Johannesson Chairman

Yvonne Mårtensson Board member Camilla Öberg Board member

Lars Henriksson Board member

Dag Andersson Chief executive officer

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 act. The information was submitted for publication, through the agency of the contact person set out below on January 27, 2022 at 7.30 am (CET).



Financial calendar

- 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
- Report on Operations 2022: Thursday January 26. 2023



PIN: 81618398#



CEO Dag Andersson and CFO Kristoffer Nordström will present the year-end report in a conference call at 2.00 p.m. CET on Thursday, January 27, 2022. Telephone SWE: +46 (0)8 566 426 51 Telephone UK: +44 3333 000804 Telephone US: +1 6319 131422



Contact

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Financial statements

Condensed Consolidated Statement of Net Income

	January-December	January-December		October-December
SEK Thousands	2021	2020	2021	<u>2020</u> 60 277
Net sales	258 386	179 861	85 863	
Cost of goods sold	-70 265	-46 886	-22 904	-18 920
Gross income	188 121	132 975	62 959	41 357
Selling expenses	-99 290	-59 899	-35 637	-19 229
Administrative expenses	-55 802	-30 342	-21 111	-11 163
Research and development expenses	-55 594	-56 178	-15 574	-15 886
Other operating revenues and expenses ¹⁾	4 067	-32 231	1 063	-9 406
Operating income	-18 498	-45 675	-8 300	-14 328
Financial income and expenses	25 163	-11 588	18 537	-11 610
Income after financial items	6 665	-57 263	10 237	-25 938
Taxes	1 487	13 528	1 952	6 363
Net income	8 152	-43 735	12 189	-19 575
Attributable to				
Parent Company's shareholders	8 152	-43 735	12 189	-19 575
Earnings per share, SEK	0,28	-1,61	0,42	-0,68
Earnings per share, SEK ²⁾	0,28	-1,60	0,41	-0,67
Average number of outstanding shares	28 845 691	27 171 352	29 241 732	28 719 136
Average number of outstanding shares ²⁾	28 936 075	27 354 518	29 615 732	29 327 136
Number of shares at closing day	29 498 666	28 719 136	29 498 666	28 719 136
Number of shares at closing day ²⁾	29 872 666	29 444 136	29 872 666	29 444 136
	13 759	-15 637	-96	-6 506
EBITDA (Operating income before depreciation and amortization)	10 / 00	-10 007	-50	-0.000
Depreciation and amortization on intangible assets	-21 219	-17 685	-5 336	-5 349
Depreciation and amortization on tangible assets	-11 038	-12 353	-2 868	-2 473
Operating income	-18 498	-45 675	-8 300	-14 328
1) See note 4 for "Other operating revenues and expenses"				

2) After dilution

Consolidated Statement of Comprehensive Income

	January-December	January-December	October-December	October-December
SEK Thousands	2021	2020	2021	2020
Net income	8 152	-43 735	12 189	-19 575
Other comprehensive income				
Items that may be reclassified to the income statement				
Exchange rate differences	22 271	-16 410	15 394	-13 179
Tax attributable to items that have been or can be transferred to net income	-	-	-	-153
Total other comprehensive income	22 271	-16 410	15 394	-13 332
Total comprehensive income	30 423	-60 145	27 583	-32 907
Attributable to				
Parent Company's shareholders	30 423	-60 145	27 583	-32 907

Condensed Consolidated Statement of Financial Position

SEK Thousands	211231	201231
ASSETS		
Goodwill	460 228	223 938
Capitalized development expenditure	456 551	393 969
Other intangible fixed assets	8 658	6 750
Fixed assets	26 297	21 334
Financial assets	43 330	41 088
Total non-current assets	995 064	687 079
Inventories	77 590	59 351
Current receivables	71 246	49 643
Liquid funds	398 696	354 236
Total current assets	547 532	463 230
Total assets	1 542 596	1 150 309
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity, attributable to the Parent Company's shareholders	1 285 450	1 008 461
Long-term interest-bearing liabilities	1 522	1 474
Long-term non-interest-bearing liabilities	151 105	66 314
Short-term interest-bearing liabilities	4 199	5 738
Short-term non-interest-bearing liabilities	100 320	68 322
Total shareholders' equity and liabilities	1 542 596	1 150 309

Condensed Consolidated Cash Flow Statement

	January-December	January-December	October-December	October-December
	2021	2020	2021	2020
Income after financial items	6 665	-57 263	10 237	-25 938
Adjustment for items not affecting cash flow	7 195	49 355	-5 087	22 720
Paid taxes	-2 701	142	-496	1 247
Change in inventories	-13 802	-14 155	-896	1 482
Change in trade receivables	-8 294	20 584	-12 825	8 051
Change in trade payables	-1 122	-10 929	8 505	-29 561
Cash flow from operating activities	-12 059	-12 266	-562	-21 999
Cash flow from investing activities	-187 703	-266 532	-125 158	-222 189
Cash flow from financing activities	234 611	482 768	236 895	-1 710
Cash flow for the period	34 849	203 970	111 175	-245 898
Liquid funds at beginning of period	354 236	159 946	284 516	608 374
Exchange rate difference in liquid funds	9 611	-9 680	3 005	-8 240
Liquid funds at end of period	398 696	354 236	398 696	354 236

Consolidated Change in Shareholders Equity

	Attribut	able to Parent Com	pany's shareho	lders	
				Retained	
				earnings incl.	Sum
		Other paid in		profit for the	shareholders
SEK Thousands	Share capital	capital	Reserves	year	equity
Shareholders´ equity as of January 1, 2020	680	515 753	16 228	44 860	577 521
Total comprehensive income January - December 2020	-	-	-16 411	-43 734	-60 145
Issuing of new shares efter deduction of incremental costs directly related to issuing new shares net of tax	54	489 640	-	-	489 694
Share warrant program	-	1 391	-	-	1 391
Shareholders' equity as of December 31, 2020	734	1 006 784	-183	1 126	1 008 461
Total comprehensive income January - December 2021	-	-	22 271	8 152	30 423
Issuing of new shares efter deduction of incremental costs directly related to issuing new shares net of tax	20	245 307	-	-	245 327
Share warrant program 1)	-	1 239	-	-	1 239
Shareholders' equity as of December 31, 2021	754	1 253 330	22 088	9 278	1 285 450

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

Condensed Consolidated Statement of Net Income per quarter

	Oct-Dec	Jul-Sep	Apr-Jun	Jan-Mar	Oct-Dec	Jul-Sep	Apr-Jun	Jan-Mar
SEK Thousands	2021	2021	2021	2021	2020	2020	2020	2020
Net sales	85 863	54 935	59 263	58 325	60 277	42 736	30 393	46 455
Cost of goods sold	-22 904	-17 000	-14 716	-15 645	-18 920	-9 602	-7 291	-11 073
Gross income	62 959	37 935	44 547	42 680	41 357	33 134	23 102	35 382
Selling expenses	-35 637	-23 344	-20 613	-19 696	-19 229	-13 470	-12 360	-14 840
Administrative expenses	-21 111	-9 053	-14 605	-11 033	-11 163	-8 462	-5 069	-5 648
Research and development costs	-15 574	-10 457	-14 034	-15 529	-15 886	-11 233	-12 186	-16 873
Other operating revenues and expenses ¹⁾	1 063	888	-4 645	6 761	-9 406	-18 631	-6 196	2 002
Operating income	-8 300	-4 031	-9 350	3 183	-14 328	-18 661	-12 709	23
Financial income and expenses	18 537	2 956	-1 411	5 081	-11 610	-481	-6 047	6 550
Income after financial items	10 237	-1 075	-10 761	8 264	-25 938	-19 142	-18 756	6 573
Taxes	1 952	-54	1 820	-2 231	6 363	4 457	2 738	-30
Net income	12 189	-1 129	-8 941	6 033	-19 575	-14 685	-16 018	6 543
Attributable to								
Parent Company's shareholders	12 189	-1 129	-8 941	6 033	-19 575	-14 685	-16 018	6 543
Earnings per share, SEK	0,42	-0,04	-0,31	0,21	-0,68	-0,51	-0,60	0,25
Earnings per share, SEK ²⁾	0,41	-0,04	-0,31	0,20	-0,67	-0,51	-0,60	0,25
Average number of outstanding shares	29 241 732	28 727 266	28 727 266	28 719 136	28 719 136	28 601 434	26 600 496	26 600 496
Average number of outstanding shares ²⁾	29 615 732	29 101 266	29 101 266	29 444 136	29 327 136	28 975 434	26 600 496	26 600 496
Number of shares at closing day	29 498 666	28 752 397	28 752 397	28 719 136	28 719 136	28 719 136	26 600 496	26 600 496
Number of shares at closing day ²⁾	29 872 666	29 126 397	29 126 397	29 444 136	29 444 136	29 093 136	26 600 496	26 600 496
EBITDA (Operating income before depreciation and amortization)	-96	4 181	-1 533	11 207	-6 506	-11 229	-5 452	7 550
Depreciation and amortization on intangible assets	-5 336	-5 278	-5 135	-5 470	-5 349	-4 114	-4 107	-4 115
Depreciation and amortization on tangible assets	-2 868	-2 934	-2 682	-2 554	-2 473	-3 318	-3 150	-3 412
Operating income	-8 300	-4 031	-9 350	3 183	-14 328	-18 661	-12 709	23
¹⁾ See note 3 for "Other operating revenues and expenses"								

¹⁾See note 3 for "Other operating revenues and expenses"

²⁾ After dilution

Consolidated Statement of Comprehensive Income per quarter

SEK Thousands	Oct-Dec 2021	Jul-Sep 2021	Apr-Jun 2021	Jan-Mar 2021	Oct-Dec 2020	Jul-Sep 2020	Apr-Jun 2020	Jan-Mar 2020
Net income	12 189	-1 129	-8 941	6 033	-19 575	-14 685	-16 018	6 543
Other comprehensive income								
Items that may be reclassified to the income statement:								
Exchange rate differences	15 394	3 163	-3 704	7 418	-13 179	-3 654	-5 226	5 649
Tax attributable to items that have been transferred, or can be transferred to net income	-	-	-	-	-153	299	319	-465
Total other comprehensive income	15 394	3 163	-3 704	7 418	-13 332	-3 355	-4 907	5 184
Total comprehensive income	27 583	2 034	-12 645	13 451	-32 907	-18 040	-20 925	11 727
Attributable to								
Parent Company's shareholders	27 583	2 034	-12 645	13 451	-32 907	-18 040	-20 925	11 727

Consolidated key ratios

	January-December	January-December	October-December	October-December
SEK Thousands	2021	2020	2021	2020
Gross margin non-Durable goods, %	76	77	77	72
Gross margin, %	73	74	73	69
EBIT, %	-7	-25	-10	-24
EBIT (adjusted), %	-1	-5	2	-2
EBITDA, %	5	-9	0	-11
EBITDA (adjusted), %	11	11	11	11
Operating margin, %	-7	-25	-10	-24
Net margin, %	3	-24	14	-32
Equity/assets ratio, %	83	88	83	88
Income per share, SEK	0,28	-1,61	0,42	-0,68
Shareholders' equity per share, SEK	43,58	35,11	43,58	35,11
Share price on closing day, SEK	279	314	279	314
Market cap on closing day, MSEK	8 215	9 018	8 215	9 018

Condensed Income Statement, Parent Company

	January-December	January-December		October-December
SEK Thousands	2021	2020	2021	2020
Net sales	161 287	134 122	36 940	37 644
Cost of goods sold	-30 757	-36 107	-6 259	-11 076
Gross income	130 530	98 015	30 681	26 568
Selling expenses	-54 003	-36 675	-19 243	-11 893
Administrative expenses	-39 907	-27 602	-9 215	-10 436
Research and development expenses	-45 372	-65 268	-11 501	-18 401
Other operating revenues and expenses	1 392	-10 074	276	2 992
Operating income	-7 360	-41 604	-9 002	-11 170
Financial income and expenses	6 475	-10 609	-1 345	-10 456
Income after financial items	-885	-52 213	-10 347	-21 626
Year end dispositions	-	4 200	-	4 200
Taxes	-181	9 577	2 794	3 380
Net income	-1 066	-38 436	-7 553	-14 046

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 19,360 thousand (19,907), of which SEK 4,777 thousand (4,929) in the quarter.

Condensed Balance Sheet, Parent Company

SEK Thousands	211231	201231
ASSETS		
Intangible fixed assets	292 229	245 777
Property, plant and equipment	8 980	5 902
Financial assets	719 916	453 598
Total non-current assets	1 021 125	705 277
Inventories	21 805	16 561
Current receivables	25 258	25 602
Cash and bank	369 479	333 318
Total current assets	416 542	375 481
Total assets	1 437 667	1 080 758
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity	1 246 317	1 000 817
Untaxed reserves	-	-
Provisions	1 499	1 311
Long-term non-interest-bearing liabilities	124 522	41 392
Short-term non-interest-bearing liabilities	65 329	37 238
Total shareholders' equity and liabilities	1 437 667	1 080 758

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 470 million (404) and SEK 100 million (68) 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 liabilities of SEK 139.3 million (-) relating to an additional purchase prices 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, non-durable goods and services. 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. Services refers to sales of organ recovery services.

				January-L	Jecember			
	Non-Durab	Non-Durable goods		Durable goods		ices	Total consolidated	
SEK Thousands	2021	2020	2021	2020	2021	2020	2021	2020
Net sales	233 971	169 425	18 365	10 436	6 050	-	258 386	179 861
Cost of goods sold	-56 923	-38 980	-10 493	-7 906	-2 849	-	-70 265	-46 886
Gross income	177 048	130 445	7 872	2 530	3 201	-	188 121	132 975
Gross margin (%)	76	77	43	24	53	-	73	74

		October-December									
	Non-Durat	ole goods	Durable	goods	Serv	ices	Total cons	solidated			
SEK Thousands	2021	2020	2021	2020	2021	2020	2021	2020			
Net sales	73 958	54 927	5 855	5 350	6 050	-	85 863	60 277			
Cost of goods sold	-16 775	-15 143	-3 280	-3 777	-2 849	-	-22 904	-18 920			
Gross income	57 183	39 784	2 575	1 573	3 201	-	62 959	41 357			
Gross margin (%)	77	72	44	29	53	-	73	69			

Note 4. Other operating revenue and expenses

	Oct-Dec	Jul-Sep	Apr-Jun	Jan-Mar	Oct-Dec	Jul-Sep	Apr-Jun	Jan-Mar
SEK Thousands	2021	2021	2021	2021	2020	2020	2020	2020
Cost of cash-based incentive program for employees outside Sweden	808	-130	-3 860	7 084	-8 332	-12 469	-	2 541
Cost of reorganization	-	-	-	-	-	-5 375	-4 498	-
Other	255	1 018	-785	-323	-1 074	-786	-1 698	-539
Total	1 063	888	-4 645	6 761	-9 406	-18 630	-6 196	2 002

Note 5. Acquisition of business

On November 9, 2021, XVIVO acquired 100 percent of the shares and votes of the US organ recovery company, STAR Teams Inc. The acquisition was made at a cash consideration of up to USD 26.1 million, with an initial payment of USD 12.3 million and potential earn-outs of a maximum of USD 13.8 million. Earn-outs are paid on condition that a combination of revenue and gross profit targets in 2023 is met. Should the targets not be met in 2023, a recovery period will begin, where the earn-out is instead based on a combination of revenue and gross profit targets in 2024.

Costs related to the acquisition amounted to SEK 10.0 million and have been charged to Administration costs in the Group's income statement during the fourth quarter of the year.

STAR Teams is a pioneer and the leading US organ recovery company, consisting of a team with more than 15 years of clinical experience, who has successfully retrieved more than 1,200 organs in the US. Currently, STAR Teams is active in lung and heart recovery and plans to expand into kidney and liver in 2022. The expansion is well in line with XVIVO's strategy to become a global provider of solutions and systems for all major organs.

The acquisition date has for administrative reasons been assumed to be 1 November and earnings and cash flow are not included in the consolidated financial statements until this date. During the period following the acquisition, STAR Teams contributed SEK 6.1 million to the Group's revenues and SEK 1.5 million to the Group's earnings in 2021. If the acquisition had occurred as of January 1, 2021, this acquisition would have totaled the Group's revenues by SEK 29.9 million and profit for the year by SEK 2.3 million.

The acquisition analysis was preliminary at the end of the fourth quarter. The following table shows preliminary acquisition analysis*.

SEK Thousands	Fair Value
Purchase price	
Paid purchase price	94 618
Holdback	10 784
Conditional additional purchase price	112 408
Total	217 810
Acquired net assets	
Intangible assets *	-
Accounts receivable and other receivables	5 946
Liquid funds	1 390
Accounts payable and other payables	-9 857
Fair value of acquired net assets	-2 521
Goodwill	220 331
Total	217 810
Impact on the Group's cash flow	
Purchase price, initial payment in cash	94 618
Less: Cash and cash equivalents in acquired company	-1 390
Impact on the Group's cash and cash equivalents	93 228

* Work to complete a full valuation of the identified acquired intangible assets is ongoing. Thus, the acquisition analysis will be adjusted once the fair values of acquired intangible assets are determined. This valuation will be completed in 2022.

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

	January-	January-	October-	October-
	December	December	December	December
SEK Thousands	2021	2020	2021	2020
Operating income	-18 498	-45 675	-8 300	-14 328
Depreciation and amortization on intangible assets	21 219	17 685	5 336	5 349
Depreciation and amortization on tangible assets	11 038	12 353	2 868	2 473
EBITDA (Operating income before depreciation and amortization)	13 759	-15 637	-96	-6 506

EBITDA (adjusted)

SEK Thousands	January- December 2021	January- December 2020	October- December 2021	October- December 2020
EBITDA (Operating income before depreciation and amortization)	13 759	-15 637	-96	-6 506
Acquisition costs	13 350	2 730	9 956	-
Integration costs	6 334	4 946	513	4 946
Cash-based incentive programs for employees outside Europe	-3 902	18 260	-808	8 332
Reorganisation costs	-	9 873	-	-
EBITDA (adjusted)	29 541	20 172	9 565	6 772

EBIT (adjusted)

	January-	January-	October-	October-
	December	December	December	December
SEK Thousands	2021	2020	2021	2020
EBIT (Operating income)	-18 498	-45 675	-8 300	-14 328
Acquisition costs	13 350	2 730	9 956	-
Integration costs	6 334	4 946	513	4 946
Cash-based incentive programs for employees outside Europe	-3 902	18 260	-808	8 332
Reorganisation costs	-	9 873	-	-
EBIT (adjusted)	-2 716	-9 866	1 361	-1 050

Gross margin

SEK Thousands	January- December 2021	January- December 2020	December	October- December 2020
Operating income				
Net sales	258 386	179 861	85 863	60 277
Operating expenses				
Cost of goods sold	-70 265	-46 886	-22 904	-18 920
Gross income	188 121	132 975	62 959	41 357
Gross margin %	73	74	73	69

Gross margin non-durable goods

SEK Thousands	January- December 2021	January- December 2020	October- December 2021	October- December 2020
Operating income				
Net sales of non-Durable goods	233 971	169 425	73 958	54 927
Operating expenses				
Cost of non-Durable goods sold	-56 923	-38 980	-16 775	-15 143
Gross income, non-Durable goods	177 048	130 445	57 183	39 784
Gross margin, non-Durable goods %	76	77	77	72

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	211231	201231
Shareholders' equity	1 285 450	1 008 461
Total assets	1 542 596	1 150 309
Equity/assets ratio %	83	88

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
Gross margin non-durable goods, %	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.
Gross margin, %	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.
EBITDA margin, %	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.
Adjusted EBITDA-margin, %	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.
Adjusted EBIT-margin, %	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.
Operating margin, %	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.
Net margin, %	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.
Equity/assets ratio, %	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.
Shareholders' equity per share, SEK	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.
Earnings per share, SEK	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.
Earnings per share after dilution, SEK	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.

Rolling 12 months	Key ratios calculated from rolling 12-month values have been calculated from the past four rolling interim reports and accounts.	Rolling 12 months gives a clearer picture of sales or profitability and a fairer picture of a key ratio's development.
Organic growth	Organic growth is sales growth from existing business operations adjusted for acquisitions and divestments. An acquisition or a sale is only included in the calculation of organic growth when it is included for an equal number of months in the present period and the corresponding period the previous year. Otherwise it is included in the calculation of acquired growth.	Organic growth excludes the effects of changes in the Group's structure, thus enabling a comparison of net sales over time.
Net sales growth in local currency	Growth in local currencies is sales growth adjusted for currency effects, which is calculated as sales for the period in local currencies recalculated at a predetermined exchange rate in relation to the corresponding period the previous year in local currencies recalculated at the same exchange rate.	As a large part of XVIVO's sales are in other currencies than the reporting currency of SEK, sales are not only impacted by actual growth, but also by currency effects. To analyse sales adjusted for currency effects, the key ratio of sales growth in local currency is used.

Glossary

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

Evaluation	Evaluation of the function of an organ
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Ex vivo (Latin for "outside a living organism")	Biological processes in living cells and tissues when they are in an artificial environment outside the body. "Opposite" of in vivo.
EVLP or (Ex Vivo Lung Perfusion)	Perfusion of a lung outside the body. The procedure is normally done to evaluate a lung before transplantation.
FDA or US Food and Drug Administration	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
HDE or Humanitarian Device Exemption	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.
Hypothermic non- ischemic perfusion of heart	Circulation of the cooled, dormant donated heart with supply of oxygen and necessary nutrients during transport to the recipient.
Durable goods	Revenues from the sale or rental of machinery for mechanical perfusion and preservation of organs.
Clinical study/trial	A study in healthy or sick people to study the effect of a drug or treatment method.
Machine perfusion	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
OPO or Organ Procurement Organization	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.
Perfusion	Passage of a fluid through an organ's blood vessels.
PMA or Premarket Approval	Premarket approval (PMA) is the FDA - process of scientific and regulatory review to evaluate the safety and efficacy of a medical device.
Preclinical study	Research performed before a drug or method of treatment is sufficiently documented to be studied in humans.
Preservation	Storage and maintenance of an organ outside the body before transplantation.
Reimbursement	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).
Static preservation	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.
Xeno-transplantation	Transplantation of living cells, tissues or organs from one species to another.
Other Sales	In terms of product category, Other sales refers to income relating to freight, service and training.

Extending horizons



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