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Heart transplant patient
Australia

Interim report January – September 2024

XVIVO Perfusion AB (publ)

XVIVO

Interim report January – September 2024

Third quarter 2024 (July 1 - September 30)

- Net sales amounted to SEK 198.5 million (146.6), corresponding to growth of 35 percent in SEK and 41 percent in local currencies. Organic growth accounted for 41 percent, and currency effects for -6 percent.
- The Business areas Thoracic and Abdominal delivered underlying organic growth adjusted for currency effects: Thoracic disposables 54 percent and Abdominal disposables 13 percent. The Services business area decreased by 7 percent.
- Gross margin for disposables was 81 percent (80). The total gross margin was 75 percent (73).
- Operating income (EBIT) amounted to SEK 20.5 million (5.3). Adjusted EBIT amounted to SEK 25.5 million (14.4).
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 37.1 million (18.9) corresponding to an EBITDA margin of 19 percent (13). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 42.1 million (28.0), corresponding to an adjusted EBITDA margin of 21 percent (19).
- Net profit amounted to SEK 85.8 million (2.3) and was impacted by financial income of SEK 65.2 million (0.1) attributable to fair value valuation of financial liabilities. Earnings per share amounted to SEK 2.72 (0.08).
- Cash flow from operating activities was SEK 22.9 million (24.8). Total cash flow amounted to SEK -21.2 million (424.4) primarily impacted by investments in R&D projects, production facilities, and investments in machine installations at clinics.

Significant events in the quarter

- XVIVO's European heart preservation study published in The Lancet
- XVIVO enters into an agreement to acquire FlowHawk - a unique communication platform for the transplant process. The transaction officially closed on October 11th
- Financial income of SEK 64.4 million recognized, attributable to write-down of financial liabilities after fair value valuation, not affecting cash flow, operating income (EBIT) or EBITDA.

The period 2024 (January 1 - September 30)

- Net sales amounted to SEK 594.9 million (441.8), corresponding to growth of 35 percent in SEK and 36 percent in local currencies. Organic growth accounted for 36 percent, currency effect -1 percent.
- All business areas delivered underlying organic growth adjusted for currency effects: Thoracic disposables 44 percent, Abdominal disposables 31 percent and Services 4 percent.
- Gross margin for disposables was 80 percent (80). The total gross margin was 74 percent (74).
- Operating income (EBIT) amounted to SEK 72.9 million (20.3). Adjusted operating income (EBIT) amounted to SEK 79.1 million (41.9).
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 124.2 million (59.8) corresponding to an EBITDA margin of 21 percent (14). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 130.1 million (81.4), corresponding to an adjusted EBITDA margin of 22 percent (18).
- Net profit increased to SEK 135.8 million (23.3) and was impacted by financial income of SEK 59.4 million (-1.7) attributable to fair value valuation of financial liabilities. Earnings per share amounted to SEK 4.31 (0.78).
- Cash flow from operating activities increased to SEK 49.2 million (28.2). Total cash flow amounted to SEK -91.7 million (341.4), primarily impacted by investments in R&D projects, production facilities, and investments in machine installations at clinics.

Significant events in the reporting period

- First-ever transplantation of a donor heart transported across the Atlantic - made possible by XVIVO's heart technology
- Study in extended hypothermic (cold) perfusion of liver using Liver Assist shows that preservation can last up to 20 hours.
- Results from XVIVO's European clinical trial, NIHP2019, in heart transplantation presented at ISHLT in Prague.
- New clinical study, 'HOPE at Heart', started by XVIVO in Europe on DCD hearts in 20 patients
- Unique initiative, 'The Bridge - Lungs for Life', started with the aim of increasing lung transplants in Sweden and Denmark

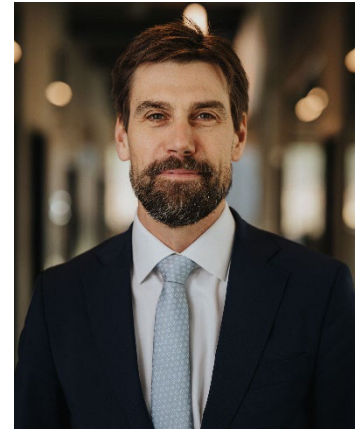
Key ratios

TSEK	January- September 2024	January- September 2023	July-September 2024	July-September 2023	Full year 2023
Net sales	594 851	441 802	198 480	146 614	597 542
Gross margin, %	74	74	75	73	74
Gross margin disposables %	80	80	81	80	81
EBIT	72 891	20 311	20 472	5 302	4 187
EBIT (adjusted) ¹⁾	79 059	41 936	25 444	14 357	42 729
EBITDA	124 185	59 791	37 099	18 931	80 537
EBITDA (adjusted) ¹⁾	130 131	81 416	42 071	27 986	102 640
Cash flow from operating activities	49 206	28 160	22 876	24 840	46 288
Earnings per share, SEK	4.31	0.78	2.72	0.08	3.07
Changes in net sales					
Organic growth in local currency, %	36	39	41	37	30
Acquired growth, %	-	6	-	5	6
Currency effect, %	-1	11	-6	9	8
Total growth, %	35	56	35	51	44

1) Adjusted for the effect of non-recurring costs of SEK 5.0 (9.1) million for the quarter. Net adjustment for the period totals SEK 5.9 (21.6) million. For specification, see Reconciliation of alternative performance measures.

Continued growth and good progress in clinical trials

The EVLP business in the US was the driving force this quarter, with our US clinical trial for heart also progressing as planned and staying within budget. Total sales in the quarter amounted to SEK 198 million (147), corresponding to growth of 41 percent in local currency. Adjusted EBITDA margin in the quarter was 21 percent (19), adjusted for M&A costs of SEK 5 million. Cashflow from operating activities was again positive, SEK 23 million (25).



Christoffer Rosenblad, CEO

As an innovative, research-driven company, I am proud that our European Randomized Controlled Trial (RCT) for heart transplantation was published in The Lancet in August. This is a strong indicator of the trial's high scientific standard and well-designed methodology, making it the first RCT for any heart perfusion device to demonstrate positive efficacy in patients.

The ongoing clinical trial for our heart technology in the US is on track to complete enrollment by Q1 2025. The swift inclusion of patients reflects the enthusiasm from centers that have used the technology. Additionally, the FDA has approved our request to increase the number of sites from 20 to 26. Within the trial, we have seen a good distribution of DCD and extended criteria DBD cases, highlighting the growing need for technologies that address the need for using more extended criteria organs.

Recently, I attended the AATS Congress (American Association for Thoracic Surgery) in Toronto, where I noted significant interest in our US heart trial amongst prominent surgeons. The increasing interest in EVLP for lungs was also evident, with many transplant clinics that had not previously conducted EVLP now showing strong interest in starting. EVLP is on the rise in the US, which is clearly reflected in our numbers for the quarter. Our global lung business had one of its best quarters ever, particularly in the US, where EVLP sales grew by 110 percent. EVLP growth is driven by increased activity and new accounts, where we can see that XVIVO is the preferred partner of choice.

As XVIVO anticipates strong growth in North America over the coming years, having a strong market presence is essential to successfully executing the company's strategy. Therefore, Mark Reade was appointed Senior Vice President North America in July and will lead the entire North American commercial team. He is also a member of XVIVO's senior management. We have now started to scale up the North American commercial footprint, both for Lung and Kidney. In addition, the importance of the Canadian market has gradually increased, and we will start to invest in Canada as early as in Q4. We have recently concluded our MDSAP¹ audit, which is key for market launch, and are expecting sales in Canada to gradually pick up in 2025.

In September, XVIVO entered into an agreement to acquire FlowHawk, a sophisticated software platform designed to automate transplant clinic's workflows. There is significant demand for

“EVLP growth is driven by increased activity and new accounts, indicating that XVIVO is the preferred partner of choice”

¹ MDSAP: Medical Device Single Audit Program

efficient communication between all parties involved, and the current lack of such systems creates an unnecessary burden for transplant teams. We want to change that. The FlowHawk software allows for direct HIPAA²-compliant communication with relevant teams, ensuring the right information is delivered to the right people at the right time. With the acquisition of FlowHawk, we are strengthening our service offering in the US, making planning and communication throughout the transplant process easier and more efficient.

Another important part of our US service offering is our established organ recovery service. The potential for this service is significant. In 2024 we continued to build a robust clinical program of high-quality standards. However, we have not yet captured the potential in terms of sales growth. Our organ recovery service is strategically aligned to support the launch of our heart technology in the US, and we will continue development of our service offering tailored to meet the needs of US clinics. Our organ recovery service, together with FlowHawk, represents an important step toward realizing our strategic ambition of becoming the preferred partner in the transplant process.

Our abdominal business had a slightly weaker quarter than usual, primarily due to lower transplant activity in key European markets. While we previously faced challenges in delivering disposables for both kidney and liver, we now have improved stock levels and are well prepared for increased transplant activity.

Sustainability is at the heart of what we do. At XVIVO, we are committed to the UN's third Sustainable Development Goal: Good Health and Well-Being, which aligns closely with our core mission. Our mission is to save more lives, improve quality of life, and make healthcare more cost-effective. In light of this, XVIVO participated in the UN's Sustainable Development Goals interviews, held in conjunction with the UN General Assembly in September in New York. The interview can be found on CNBC.com³.

With one quarter remaining in the year, we are in a strong position and eagerly await European regulatory approval, the CE mark, for our heart technology. As we accelerate the launch of Kidney Assist Transport, we are also strengthening our service offering by enhancing our digital presence with FlowHawk. With strong momentum in our US lung business, we enter the final part of the year with confidence. We are committed to invest in the need for more transplants as we steadily move closer to realizing our vision that nobody should die waiting for a new organ.

Christoffer Rosenblad, CEO

² HIPAA: Healthcare Insurance Portability and Accountability Act

³ <https://www.cnbc.com/advertorial/acumen/#xvivo-organ-transplantation>

This is XVIVO

Founded in 1998, XVIVO is the only MedTech 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 organ transplantation. XVIVO is a global company headquartered in Gothenburg, Sweden. The company is listed on Nasdaq Stockholm.

Business concept and goals

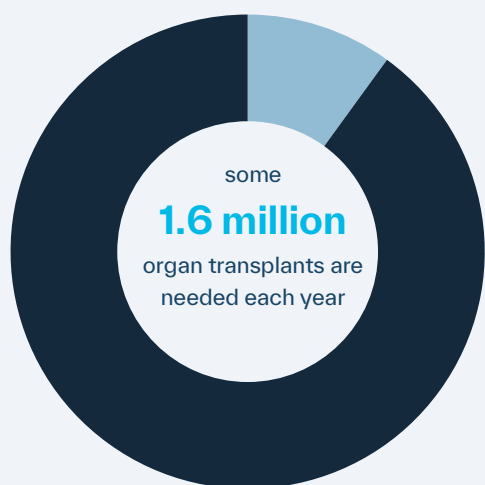
XVIVO's business concept is to develop and market effective, innovative technology for preserving, transporting and assessing organs outside the body while awaiting transplant, and to facilitate the transplant process by offering services in the form of organ recovery and organ perfusion.

Our goals

To become the world leader in the preservation of organs outside the body for all major organs (lung, heart, liver and kidney) and establish machine perfusion as the standard method for preserving, transporting and assessing donated organs ahead of transplantation.

Purpose and vision

We believe in an extended life of organs. Nobody should die waiting for a new organ.



With only

160,000

organ transplants each
year, only

10%

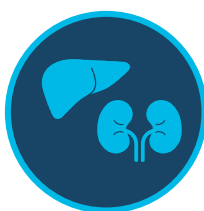
of total global demand
is met

XVIVO's offering increases
availability of transplantable
organs

Our business areas



Thoracic



Abdominal



Services

Compilation of net sales and EBITDA

SEK Thousands	January-September 2024	January-September 2023	July-September 2024	July-September 2023	January-December 2023
Net Sales Thoracic	403 012	285 908	140 866	90 884	384 363
Net Sales Abdominal	129 763	95 866	39 203	35 118	134 039
Net Sales Services	62 076	60 028	18 411	20 612	79 140
Net Sales Total	594 851	441 802	198 480	146 614	597 542
Gross income Thoracic	333 632	238 483	116 048	77 644	321 877
Gross margin Thoracic, %	83%	83%	82%	85%	84%
Gross income Abdominal	84 038	62 112	24 895	21 717	88 088
Gross margin Abdominal, %	65%	65%	64%	62%	66%
Gross income Services	23 611	27 282	6 988	8 237	35 146
Gross margin Services, %	38%	45%	38%	40%	44%
Gross income Total	441 281	327 877	147 931	107 598	445 111
Gross margin Total, %	74%	74%	75%	73%	74%
Selling expenses	-202 999	-167 457	-67 474	-66 554	-232 261
Administrative expenses	-72 923	-59 635	-28 452	-13 392	-76 944
Research and development expenses	-92 521	-84 928	-30 863	-27 126	-135 942
Other operating revenues and expenses	53	4 454	-670	4 776	4 223
Operating Income	72 891	20 311	20 472	5 302	4 187
Amortization and depreciation cost of goods sold	1 398	311	443	86	726
Amortization and depreciation selling expenses	18 085	3 227	6 030	1 134	19 000
Amortization and depreciation administrative expenses	3 830	26 688	1 209	9 060	4 447
Amortization, depreciation and write-down research and development expenses	27 981	9 254	8 945	3 349	52 177
EBITDA (Operating income before depreciation and amortization)	124 185	59 791	37 099	18 931	80 537
EBITDA, %	21%	14%	19%	13%	13%
EBITDA (adjusted) 1)	130 131	81 416	42 071	27 986	102 640
EBITDA (adjusted), %	22%	18%	21%	19%	17%

1) Adjusted for the effect of non-recurring costs of SEK 5.0 (9.1) million for the quarter. Net adjustment for the period totals SEK 5.9 (21.6) million. For specification, see Reconciliation of alternative performance measures.

Summary

The quarter July - September 2024

Net sales and income

Net sales in the quarter amounted to SEK 198.5 million (146.6), an increase of 35 percent year-on-year, corresponding to organic growth of 41 percent. For a description of developments in each business area, see pages 12-14.

The total gross margin for the quarter was 75 percent (73). For comments regarding the margins in each business area, see pages 12-14.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 37.1 million (18.9) corresponding to an EBITDA margin of 19 percent (13). EBITDA was affected by acquisition and integration costs of SEK -5.0 million (-9.1). Adjusting for these items, EBITDA amounted to SEK 42.1 million (28.0), corresponding to an adjusted EBITDA margin of 21 percent (19).

Operating income (EBIT) amounted to SEK 20.5 million (5.3). EBIT adjusted for the aforementioned costs amounted to SEK 25.5 million (14.4).

Selling expenses in relation to total sales amounted to 34 percent (45) for the quarter. R&D expenses amounted to 16 percent (19) of sales. Administrative expenses amounted to 14 percent (9), affected by acquisition costs. XVIVO will continue to invest in the organization, marketing activities and development over the coming years in order to meet strong demand.

Net profit amounted to SEK 85.8 million (2.3) and was impacted by financial income of SEK 65.2 million (0.1) attributable to fair value valuation (write-down) of financial liabilities related to potential earn-out payments for acquisitions. The item did not affect operating income (EBIT), EBITDA or cash flow.

Capitalization and amortization

During the quarter, SEK 30.3 million (21.5) of development expenses were capitalized as intangible assets. Development expenses essentially related to expenses for R&D projects with the aim of obtaining regulatory approvals in the US and Europe in heart and liver perfusion. Amortization of capitalized development expenditure amounted to SEK 6.8 million (7.3) in the quarter.

Cash flow

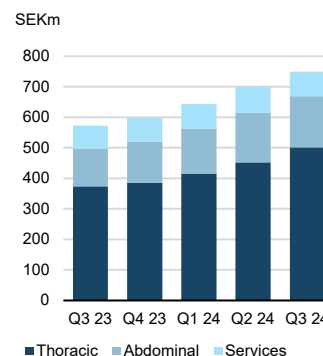
Cash flow from operating activities in the quarter amounted to SEK 22.9 million (24.8), positively affected by strong sales and strengthened EBITDA, but weighed down by increased capital tied up due to strong sales.

Cash flow from investing activities amounted to SEK -41.5 million (-28.1), of which SEK -30.7 million (-21.7) was invested in intangible assets and SEK -10.8 million (-6.5) was invested in property, plant and equipment.

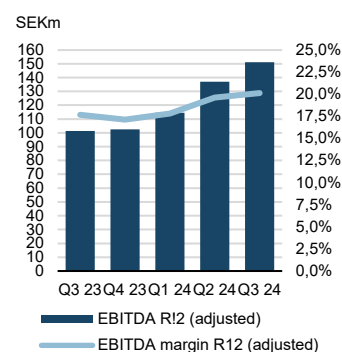
Cash flow from financing activities amounted to net SEK -2.6 million (427.6). Exchange rate differences impacted the cash flow for the quarter by SEK -9.6 million (-1.6).

Cash and cash equivalents at the end of the quarter amounted to SEK 450.0 million (594.3).

Net sales by business area (R12)



EBITDA and EBITDA margin (adjusted, R12)



Significant events during the quarter

Results of XVIVO's European heart preservation study published in The Lancet

In the quarter, the results of the European randomized controlled clinical trial investigating the use of XVIVO's heart technology were published in the prestigious scientific journal The Lancet⁴. The trial compared outcomes for patients who received a donor heart preserved either on ice, the current standard method, or using XVIVO's Heart Assist Transport device. The primary outcome demonstrated a clinically important 44 percent reduced risk of severe complications after transplantation, driven by a 61 percent reduction in primary graft dysfunction (PGD) when XVIVO's heart technology was implemented. The clinical trial included 204 patients across 15 trial sites in 8 European countries.

XVIVO to acquire FlowHawk – a unique communication platform for the transplant process

XVIVO has entered into an agreement to acquire the transplant clinical workflow automation business, including the development and distribution of the FlowHawk software platform, from Healthtech Solutions Inc. dba OmniLife. Under the terms of the transaction, OmniLife's two co-founders, along with two sales representatives, will join XVIVO. Following a customary set of conditions for an asset deal being fulfilled, the transaction officially closed in October 2024.

100 percent of the initial purchase price for the acquisition of the assets related to FlowHawk corresponds to USD 6.0 million and was paid in cash at closing of the transaction on October 11th, financed with existing company funds. An additional milestone payment of USD 1.0 million is to be paid out in the first half of 2026 provided certain performance-based targets are met during 2025. One-time costs associated with the transaction amounted to SEK 5 million and recognized in the third quarter. Integration is expected to be completed during the first half of 2025, with additional one-time costs of approximately SEK 5 million.

Financial income of SEK 64 million from fair value of financial liabilities

Write-downs of financial liabilities relating to additional purchase consideration for acquired businesses had a positive impact of SEK 64.4 million (4.1) on the Income Statement in the quarter. The change was recognized under financial income and expenses, and did not affect operating income (EBIT), EBITDA or cashflow. Nor did the assessment result in any need for write-downs of intangible assets associated with acquisitions.

⁴ [https://doi.org/10.1016/S0140-6736\(24\)01078-X](https://doi.org/10.1016/S0140-6736(24)01078-X)

The period January - September 2024

Net sales and income

Sales in the period amounted to SEK 594.9 million (441.8), an increase of 35 percent year-on-year, equivalent to organic growth of 36 percent. For a description of developments in each business area, see pages 12-14.

The total gross margin for the period was 74 percent (74). For comments regarding the margins in each business area, see pages 12-14.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 124.2 million (59.8) corresponding to an EBITDA margin of 21 percent (14). EBITDA was affected by acquisition and integration costs of SEK -5.9 million (-21.6). Adjusting for these items, EBITDA amounted to SEK 130.1 million (81.4), corresponding to an adjusted EBITDA margin of 22 percent (18).

Operating income (EBIT) amounted to SEK 72.9 million (20.3). EBIT adjusted for the aforementioned costs and impairment of intangible assets amounted to SEK 79.1 million (41.9).

Selling expenses as a proportion of sales amounted to 34 percent (38) in the period. R&D expenses amounted to 16 percent (19) of sales. Administration expenses amounted to 12 percent (13) of sales. XVIVO will continue to invest in organization, marketing activities and development over the coming years in order to meet strong demand.

Net profit amounted to SEK 135.8 million (23.3) and was impacted by financial income of SEK 59.4 million (-1.7) attributable to fair value valuation (write-down) of financial liabilities related to potential earn-out payments for acquisitions. The item did not affect operating income (EBIT), EBITDA or cash flow.

Capitalization and amortization

During the period, SEK 82.5 million (66.9) of development expenses were capitalized as intangible assets. Development expenses essentially relate to expenses for R&D projects with the aim of obtaining regulatory approvals in the US and Europe. Amortization of capitalized development expenditure amounted to SEK 21.7 million (21.8) in the period.

Cash flow

Cash flow from operating activities was SEK 49.2 million (28.2) in the period. Cash flow from investing activities amounted to SEK -132.4 million (-109.0), of which SEK -84.0 million (-67.6) was invested in intangible assets and SEK -48.5 million (-23.7) was invested in property, plant and equipment.

Cash flow from financing activities amounted to net SEK -8.5 million (422.3).

Cash and cash equivalents at the end of the period amounted to SEK 450.0 million (594.3).

Financing

XVIVO's operations shall be conducted with a sustainable and efficient capital structure. The company's equity/assets ratio is strong and amounted to 91 percent (86) at the end of the period.

Net sales

**SEK 595
million**

Gross margin

74%

Adjusted EBITDA

22%

Significant events in the reporting period

First-ever transplantation of a donor heart transported across the Atlantic - made possible by the use of XVIVO's heart technology

For the first time in medical history, transportation of a donor heart was performed across the Atlantic Ocean. This was achieved via a commercial flight with Air France, and XVIVO Heart Assist Transport preserved the heart during transport in economy class. The result was presented in *The Lancet*⁵ in the first quarter of the year. After preservation outside the body for more than 12 hours using XVIVO's Heart Assist Transport a successful transplantation was performed by the Pitié-Salpêtrière Hospital in Paris in January - impossible with conventional methods but made possible by the use of XVIVO's heart technology. The recipient was a 71-year-old patient, and the donor was 48 years old.

A recently published study in the *Lancet* 6 demonstrated that Liver Assist enables extended perfusion times of liver of up to 20 hours - increasing the efficiency of hospital planning and logistics.

A recently published clinical trial conducted by the UMCG in Groningen, the Netherlands, showed that XVIVO's Liver Assist has the potential to reshape liver transplant logistics. The trial showed that donor livers could be transplanted with consistently good outcomes after up to 20 hours of preservation using DHOPE (double hypothermic non-ischemic machine organ perfusion organ). For the first time, this provides transplant clinics with the opportunity to plan the timing of a transplant and to avoid nighttime surgery. By extending perfusion times, in 2023 UMCG was able to perform the majority of all liver transplants during daytime hours rather than at night.

Results from XVIVO's European clinical trial NIHP2019 for heart preservation presented at ISHLT in Prague

The results from XVIVO's clinical trial, NIHP2019, in heart transplantation were presented at the 2024 International Society of Heart and Lung Transplantation meeting in Prague, Czech Republic, in April.

The results showed that the primary endpoint, representing severe complications after heart transplantation, was registered in 18.8% of the subjects who received a donor heart preserved with XVIVO Heart Assist Transport. In the control group, who received a donor heart transported on ice, the current standard method for heart preservation, 30.1% of subjects suffered from severe complications. The rates of severe primary graft dysfunction (PGD) after heart transplantation were also significantly lower for patients who received a donor heart preserved with XVIVO Heart Assist Transport (11% compared to 28%).

The NIHP2019 trial is a randomized, controlled, open label, multicenter clinical investigation of XVIVO Heart Assist Transport to collect the safety and performance data required to support CE marking. The NIHP2019 trial enrolled 203 patients in 15 institutions across 8 European countries between November 2020 and May 2023.

New clinical study started by XVIVO in Europe in DCD hearts - 'Hope at Heart'

A new European study in direct procurement of DCD hearts was approved to start in Belgium. The study will also include transplantation clinics in the Netherlands. This is a unique study, as the potential for direct procurement of DCD hearts followed by cold oxygenated perfusion (HOPE) has never previously been explored. Earlier HOPE studies have shown positive results in both liver and kidney from DCD donors. Twenty patients will be included in the study, which is led by Prof. Filip Rega, who was also the clinical lead in XVIVO's European randomized heart preservation trial (NIHP2019).

'The Bridge – Lungs for Life' – a unique initiative aimed at increasing lung transplants in Sweden and Denmark

A centralized model for evaluating lungs with EVLP can enable utilization of more available lungs and give more patients access to life-changing transplantations. Under this initiative, EVLP is carried out using XVIVO's XPS technology at Rigshospitalet in Copenhagen, Denmark. In addition to lungs from donors in Denmark, lungs will also be received from the University Hospital of Skåne in Lund, Sweden. This is the first collaboration of its kind in Europe that involves lungs transported across national borders. The Copenhagen hub will be developed with financial support from the EU, with the aim of transplantation clinics throughout Scandinavia eventually receiving EVLP lungs from the hub. A strengthened collaboration would increase efficiency and save more lives.

⁵ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(24\)00258-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)00258-7/fulltext)

⁶ [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(25\)00588-6/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(25)00588-6/fulltext)

Business area development

XVIVO's operations are conducted in three business areas: Thoracic (products for lung and heart transplantation), Abdominal (products and perfusion services for liver and kidney transplantation) and Services (organ recovery). Commercial and R&D activities take place within each business area.

Thoracic

The Thoracic business area comprises XVIVO's products for lung and heart transplantation. 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 regulatory approval in all major markets and in 2019 they were the first products to receive US FDA clearance for warm perfusion of marginal lungs. In heart transplantation, XVIVO's products are in a clinical study phase. Some sales in heart transplantation started in 2023: in Australia and New Zealand through a special license (compassionate use), and in the US where XVIVO is permitted to charge for products used in the clinical heart preservation study.

Summary

SEK Thousands	January-September 2024	January-September 2023	July-September 2024	July-September 2023	Full year 2023
Net sales	403 012	285 908	140 866	90 884	384 363
Disposables	391 687	274 888	133 071	89 833	372 518
Machines	11 325	11 020	7 795	1 051	11 845
Gross margin, %	83	83	82	85	84
Disposables	84	85	85	86	85
Machines	31	37	30	22	39

The quarter July - September 2024

Thorax presented a record quarter driven by strong progress in the US. Sales amounted to SEK 140.9 million (90.9), equivalent to growth of 55 percent year-on-year or 62 percent adjusted for currency effects. Sales of disposables delivered organic growth of 54 percent.

Machine perfusion accounted for 63 percent (46) of net sales. Growth was primarily driven by strong momentum for EVLP on the US market, which increased by as much as 110 percent, plus accelerating sales of heart products within the framework of the US study. Static preservation and other sales accounted for the remainder of net sales.

Gross margin for disposables was 85 percent (86).

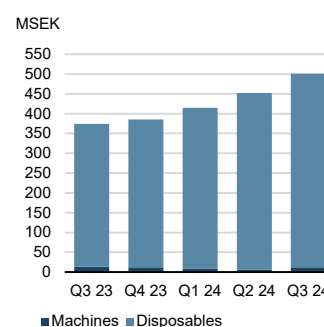
The period January - September 2024

Sales increased by 41 percent in the period compared to the corresponding period in the previous year and amounted to SEK 403.0 million (285.9). The increase is equivalent to an increase of 43 percent adjusted for currency effects.

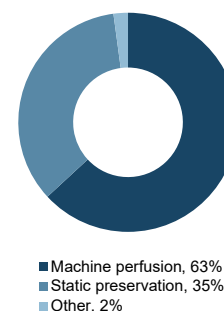
Sales of disposables increased by 42 percent and amounted to SEK 391.7 million (274.9). Organic growth amounted to 44 percent in local currencies. Machine perfusion accounted for 60 percent (50) of net sales. Static preservation and other sales accounted for the remainder of net sales.

Gross margin for disposables was 84 percent (85).

Net sales Thoracic (R12)



Net sales per product category Thoracic (Q3)



Abdominal

The Abdominal business area comprises XVIVO's product and service operations in liver and kidney transplantation. XVIVO offers oxygenated machine perfusion products for both these organs. Products for liver and kidney transplants are primarily sold in selected markets in Europe, but also in other smaller markets. The launch of the company's kidney preservation product, Kidney Assist Transport, gradually accelerated during 2024.

Summary

SEK Thousands	January-September 2024	January-September 2023	July-September 2024	July-September 2023	Full year 2023
Net sales	129 763	95 866	39 203	35 118	134 039
Disposables	110 430	85 490	33 702	30 821	118 342
Machines	19 333	10 376	5 501	4 297	15 697
Gross margin, %	65	65	64	62	66
Disposables	64	65	62	61	66
Machines	69	67	74	70	67

The quarter July - September 2024

Sales amounted to SEK 39.2 million (35.1) in the quarter, which is equivalent to an increase of 12 percent year-on-year. Adjusted for currency effects, growth totaled 16 percent. The increase for disposables totaled 9 percent, or 13 percent adjusted for currency effects. The revenue was primarily generated in Europe, and approximately 72 percent related to liver perfusion.

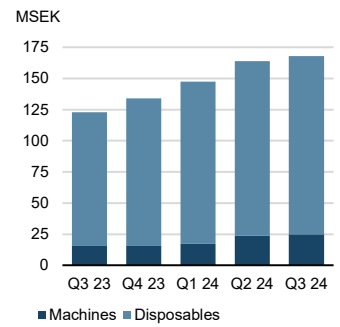
The gross margin for disposables was 62 percent (61). Margins are expected to improve at a pace with increased US sales and as we achieve economies of scale from new production facilities in 2025.

The period January - September 2024

Sales in the period amounted to SEK 129.8 million (95.9), equivalent to growth of 35 percent year-on-year. Growth was 37 percent adjusted for exchange rate effects. The increase for disposables totaled 29 percent, or 31 percent adjusted for currency effects.

The gross margin for disposables was 64 percent (65).

Net sales Abdominal (R12)



Net sales by product category, Abdominal (Q3)



Services

The Services business area comprises XVIVO's organ recovery operations in the US in the area of donated hearts and lungs. Organ recovery refers to the removal of organs from the donor body, the preservation of organs in cold fluid during transport, and logistics and coordination ahead of and during organ recovery.

Organ recoveries in Q3

96

Summary

SEK Thousands	January-September 2024	January-September 2023	July-September 2024	July-September 2023	Full year 2023
Net sales	62 076	60 028	18 411	20 612	79 140
Gross margin, %	38	45	38	40	44

The quarter July - September 2024

Sales amounted to SEK 18.4 million (20.6), a year-on-year decrease of 7 percent adjusted for currency effects, mainly due to lower activity in a couple of clinics. The qualitative offering was strengthened by the implementation of FlowHawk in the quarter, and discussions are underway to extend partnerships that further strengthen the logistical offering.

Gross margin decreased to 38 percent (40), as surgical capacity is retained during temporary dips in activity. Margins are expected to improve gradually as activity increases and new contracts are signed.

The period January - September 2024




Sales grew organically by 4 percent in year-on-year terms, despite the fact that the number of organ recoveries decreased. The contract renegotiations that took place in 2023 thus contributed to improved profitability, and XVIVO has now achieved a profitable service model.

Gross margin amounted to 38 percent (45). Margins are expected to improve gradually as activity increases and new contracts are signed.


Demand for organ recovery services from US clinics is good and XVIVO's operations are equipped for growth.

R&D portfolio

Development projects

Project	Description	Status
<p>Heart transplantation</p> 	<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, coupled with the time a donated heart can survive outside the body.</p> <p>In collaboration with Professor Stig Steen, XVIVO has developed a comprehensive solution comprising fluids and machinery that prevents damage to the heart and preserve its function during transport. The technology contributes to improved results after heart transplantation and enables longer transports. The results from the transplant of donated hearts transported and preserved with XVIVO's method are currently being evaluated in ongoing clinical trials.</p>	<p>In the quarter, the results from XVIVO's European multicenter study with 15 participating clinics were published in the Lancet. The benefit of preserving donated hearts with XVIVO's technology was reflected in a significant decrease in serious complications in the first 30 days after transplantation. The first unique cases where XVIVO's heart technology was successfully used in DCD were also presented in the quarter.</p> <p>In the first quarter 2024, a donated heart was transported across the Atlantic Ocean for the first time in medical history. The donated heart was preserved outside the body for more than 12 hours - unthinkable using conventional methods but made possible with XVIVO's heart technology. Heart function was immediately good after transplantation.</p> <p>In the second quarter 2023, the FDA approved XVIVO's IDE application for the planned clinical trial, as well as approving the inclusion of DCD hearts. The study, which included its first patients in the third quarter 2023, is attracting very substantial interest from transplantation clinics, and patient recruitment continues at a positive rate and according to plan.</p>
<p>Kidney transplantation</p> 	<p>As with other organs, there is a shortage of transplantable kidneys. Studies have demonstrated that transporting kidneys with ongoing oxygenated perfusion improves post-transplant outcomes. New areas that are being explored include the role of warm perfusion for purposes of evaluation.</p>	<p>The evidence for perfusion of donated kidneys was recently summarized in an extensive Cochrane review. The benefits of oxygenated perfusion were especially emphasized. This technology is unique to XVIVO. This step has taken kidney technology into a more mature phase, although development remains ongoing. The combination of new perfusion technology with warm perfusion and new solutions is the focus of research in the field of organ transplantation, and several investigator-initiated studies of both cold and warm perfusion are ongoing.</p>
<p>Liver transplantation</p> 	<p>As with other organs, there is a shortage of transplantable livers. By optimizing the process for preserving and evaluating the function of the donated liver, more organs with good function potentially become available for transplant. Studies show that cold oxygenated perfusion of liver before transplantation clearly reduces the risk of serious complications in many cases. The use of warm perfusion with XVIVO's technologies with the aim of evaluating liver function outside the body ahead of transplant has attracted significant interest over the past year.</p>	<p>A large number of randomized clinical trials and an extensive Cochrane review show proven clinical benefits for patients when using XVIVO's cold perfusion technology (HOPE). Recently published studies have shown that perfusion of liver with XVIVO's technology enables transplantations to be scheduled during daytime hours, which benefits both patients and transplantation teams.</p> <p>In order to gain approval for the liver technology in the US, XVIVO is preparing for clinical trials in the US and discussions with the FDA are ongoing.</p>

Research projects

Project	Description	Status
<p>Xenotransplantation</p> 	<p>Xenotransplantation involves the use of non-human organs in transplantation. The method is currently at the research stage for several organs.</p>	<p>The first successful transplantation to a human was performed in January 2022, with a further transplant performed in September 2023. In both cases, XVIVO's heart technology to preserve the heart before transplantation. XVIVO will continue to support groundbreaking research in the area and our technology for preserving heart function is currently used by three world-leading research teams in xenotransplantation.</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. It includes guidelines for business principles, human rights and working principles. For more detailed information regarding our sustainability work, see the company's Annual Report for 2023. The Annual Report and our key policies are available at www.xvivogroup.com.

Organization and employees

The XVIVO Group has 161 employees, of whom 81 are women and 80 men. Of these, 54 are employed in Sweden and 107 outside Sweden. The head office is located in Gothenburg, Sweden and our subsidiaries are located in the US, Netherlands, Italy, France, Brazil, Australia and China. XVIVO also has employees based in several other countries in Europe.

Related-party transactions

There were no related-party transactions 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 high-quality, efficient and safe products. The number of organ transplants is marginally affected by seasonal effects. Mainly in new treatment methods, such as warm perfusion of lungs, slightly less activity occurs during the summer months because there is less training and learning during the summer vacation period. 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 operational risks for the Group can be found in the Administration Report which is part of the Annual Report for 2023, available at www.xvivogroup.com.

Nomination Committee for the 2025 AGM

The following have been appointed to be part of XVIVO Perfusion AB's (publ) Nomination Committee for the 2025 Annual General Meeting:

Henrik Blomquist, appointed by Bure Equity AB
Thomas Ehlin, appointed by Fjärde AP-fonden
Martin Lewin, appointed by Eccenovo AB (publ)
Gösta Johannesson, Chairman of the Board

They were appointed in accordance with the instructions regarding the principles for appointing a Nomination Committee adopted at the Annual General Meeting of XVIVO Perfusion AB (publ) on April 27, 2018. The shareholders who appointed the members of the Nomination Committee jointly represented 28.7 percent of all shares in the company on August 31, 2024.

Annual General Meeting and Annual Report

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on April 25, 2025, in Gothenburg. Shareholders who wish to have a matter dealt with at the meeting may request this in writing from the Board of Directors. Any such request for consideration of a matter shall be sent to XVIVO Perfusion AB (publ), FAO: The Nomination Committee, Gemenskapens gata 9, SE-431 53 Mölndal, Sweden, and must be received by the Board of Directors no later than seven weeks before the meeting, or at least in time that the matter, if necessary, can be included in the notice convening the meeting. The Annual Report for 2024 is expected to be available to download from the XVIVO website in the week beginning March 31, 2025.

Outlook

There is a constantly growing need for new organs globally and XVIVO assesses that demand is currently ten times greater than the supply of transplantable organs. One solution for increasing the number of transplantable organs is the use of machine perfusion, which is increasingly becoming the standard procedure. We also see growing demand for service models, both in terms of scope and significance. Due to growing interest in our product and service offering across all organ areas, we anticipate continued long-term sustainable growth.

As we enter the fourth quarter of the year, we continue to focus on growth and investment in our machine perfusion and service models while successfully executing clinical multicenter studies in the US (heart and liver). We are looking forward to 2025, a year that will bring important milestones, including the commercialization of our heart technology in Europe and Australia, and the inclusion of the final patient in the US heart trial. Additionally, we will begin producing our first disposable kits within our new production set-up, which will increase our future delivery capacity of disposables to ten times the current level.

Although XVIVO and the transplantation industry in general are returning significant growth, there is continued uncertainty in the surrounding world. The Covid-19 pandemic showed that global transplantation activity is negatively affected by health crises that place healthcare services under significant pressure. Geopolitical conflict and war in the surrounding world are having a limited impact on XVIVO's operations. We have very limited sales exposure to countries affected by conflict and the procurement chain is not exposed to currently known war zones. We assess that the number of transplants in the world will continue to increase. Growth will be fueled by machine perfusion and service models that facilitate the work of transplantation clinics, and XVIVO will continue to invest in the significant existing market potential.

Significant events after the end of the period

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

This report was submitted by the CEO on behalf of the Board.

Mölnadal, October 24, 2024

Christoffer Rosenblad
CEO

This report has been reviewed by the company's auditors.

This information is information that XVIVO Perfusion AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication through the agency of the contact person set out below on October 24, 2024 at 7.30 am CET.



Financial calendar

- Year-End Report 2024:
Tuesday, January 28, 2025
- Interim Report January-March 2025:
Thursday, April 24, 2025
- Interim Report January-June 2025:
Friday, July 11, 2025
- Interim Report January-September
2025: Thursday, October 23, 2025



Conference call

CEO Christoffer Rosenblad and CFO Kristoffer Nordström will present the Interim Report in a conference call at 2.00 p.m. CET on October 24.

For access via conference call, click [here](#)

For access via webcast, click [here](#)



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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 2024 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, Sweden, October 24, 2024

KPMG AB

Daniel Haglund

Authorized Public Accountant

Financial statements

Condensed Consolidated Statement of Net Income

SEK Thousands	January-September 2024	January-September 2023	July-September 2024	July-September 2023	January-December 2023
Net sales	594 851	441 802	198 480	146 614	597 542
Cost of goods sold	-153 570	-113 925	-50 549	-39 016	-152 431
Gross income	441 281	327 877	147 931	107 598	445 111
Selling expenses	-202 999	-167 457	-67 474	-66 554	-232 261
Administrative expenses	-72 923	-59 635	-28 452	-13 392	-76 944
Research and development expenses	-92 521	-84 928	-30 863	-27 126	-135 942
Other operating revenues and expenses	53	4 454	-670	4 776	4 223
Operating income	72 891	20 311	20 472	5 302	4 187
Financial income and expenses	77 441	8 648	67 207	-4 348	90 334
Income after financial items	150 332	28 959	87 679	954	94 521
Taxes	-14 537	-5 613	-1 862	1 330	-2 701
Net income	135 795	23 346	85 817	2 284	91 820
Attributable to					
Parent Company's shareholders	135 795	23 346	85 817	2 284	91 820
Earnings per share, SEK	4.31	0.78	2.72	0.08	3.07
Earnings per share, SEK ¹⁾	4.29	0.78	2.71	0.08	3.07
Average number of outstanding shares	31 499 470	29 935 147	31 499 470	30 139 116	29 935 147
Average number of outstanding shares ¹⁾	31 628 915	29 935 147	31 685 836	30 139 116	29 935 147
Number of shares at closing day	31 499 470	31 499 470	31 499 470	31 499 470	31 499 470
Number of shares at closing day ¹⁾	31 628 915	31 499 470	31 685 836	31 499 470	31 499 470
EBITDA (Operating income before depreciation and amortization)	124 185	59 791	37 099	18 931	80 537
Depreciation and amortization on intangible assets	-27 668	-23 073	-8 732	-7 725	-53 098
Depreciation and amortization on tangible assets	-23 626	-16 407	-7 895	-5 904	-23 252
Operating income	72 891	20 311	20 472	5 302	4 187

¹⁾ After dilution

Consolidated Statement of Total Comprehensive Income

SEK Thousands	January-September 2024	January-September 2023	July-September 2024	July-September 2023	January-December 2023
Net income	135 795	23 346	85 817	2 284	91 820
Other comprehensive income					
Items that may be reclassified to the income statement					
Exchange rate differences	-3 337	25 051	-30 987	-10 520	-26 897
Total other comprehensive income	-3 337	25 051	-30 987	-10 520	-26 897
Total comprehensive income	132 458	48 397	54 830	-8 236	64 923
Attributable to					
Parent Company's shareholders	132 458	48 397	54 830	-8 236	64 923

Condensed Consolidated Statement of Financial Position

SEK Thousands	240930	230930	231231
ASSETS			
Goodwill	597 640	645 409	591 392
Capitalized development expenditure	661 508	593 627	598 505
Other intangible fixed assets	26 461	8 029	30 461
Fixed assets	121 714	78 193	97 552
Financial assets	42 810	38 231	51 295
Total non-current assets	1 450 133	1 363 489	1 369 205
Inventories	190 122	145 618	141 604
Current receivables	187 956	133 740	138 713
Liquid funds	449 982	594 261	546 088
Total current assets	828 060	873 619	826 405
Total assets	2 278 193	2 237 108	2 195 610
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity, attributable to the Parent Company's shareholders	2 083 175	1 928 115	1 945 045
Long-term interest-bearing liabilities	14 742	16 070	21 169
Long-term non-interest-bearing liabilities	29 500	150 857	94 908
Short-term interest-bearing liabilities	9 835	9 455	10 268
Short-term non-interest-bearing liabilities	140 941	132 611	124 220
Total shareholders' equity and liabilities	2 278 193	2 237 108	2 195 610

Condensed Consolidated Cash Flow Statement

	January-September 2024	January-September 2023	July-September 2024	July-September 2023	January-December 2023
Income after financial items	150 332	28 959	87 679	954	94 521
Adjustment for items not affecting cash flow	-11 999	31 953	-45 921	19 782	-1 992
Paid taxes	-7 493	-3 365	-3 199	-1 830	-7 017
Change in inventories	-45 518	-34 141	-17 782	-22 702	-33 481
Change in trade receivables	-45 071	-13 047	-15 643	-338	-25 034
Change in trade payables	8 955	17 801	17 742	28 974	19 291
Cash flow from operating activities	49 206	28 160	22 876	24 840	46 288
Cash flow from investing activities	-132 418	-109 034	-41 484	-28 087	-161 619
Cash flow from financing activities	-8 508	422 273	-2 618	427 626	418 547
Cash flow for the period	-91 720	341 399	-21 226	424 379	303 216
Liquid funds at beginning of period	546 088	246 545	480 768	171 437	246 545
Exchange rate difference in liquid funds	-4 386	6 317	-9 560	-1 555	-3 673
Liquid funds at end of period	449 982	594 261	449 982	594 261	546 088

Consolidated Changes in Shareholders' Equity

SEK Thousands	Attributable to Parent Company's shareholders				Sum shareholders' equity
	Share capital	Other paid in capital	Reserves	Retained earnings incl. profit for the year	
Shareholders' equity as of January 1, 2023	762	1 313 839	87 781	27 754	1 430 136
Total comprehensive income January - September 2023	-	-	25 051	23 346	48 397
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	43	448 019	-	-	448 062
Accounting effect of incentive programs according to IFRS 2	-	1 520	-	-	1 520
Shareholders' equity as of September 30, 2023	805	1 763 378	112 832	51 100	1 928 115
Total comprehensive income October - December 2023	-	-	-51 948	68 474	16 526
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	-	-479	-	-	-479
Accounting effect of incentive programs according to IFRS 2	-	883	-	-	883
Shareholders' equity as of December 31, 2023	805	1 763 782	60 884	119 574	1 945 045
Total comprehensive income January - September 2024	-	-	-3 337	135 795	132 458
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	-	-	-	-	-
Accounting effect of incentive programs according to IFRS 2	-	5 672	-	-	5 672
Shareholders' equity as of September 30, 2024	805	1 769 454	57 547	255 369	2 083 175

Condensed Consolidated Statement of Net Income by quarter

SEK Thousands	Jul-Sep 2024	Apr-Jun 2024	Jan-Mar 2024	Oct-Dec 2023	Jul-Sep 2023	Apr-Jun 2023	Jan-Mar 2023	Oct-Dec 2022
Net sales	198 480	210 349	186 022	155 740	146 614	154 573	140 615	131 514
Cost of goods sold	-50 549	-52 105	-50 916	-38 506	-39 016	-39 111	-35 798	-36 657
Gross income	147 931	158 244	135 106	117 234	107 598	115 462	104 817	94 857
Selling expenses	-67 474	-70 941	-64 584	-64 804	-66 554	-52 528	-48 375	-45 718
Administrative expenses	-28 452	-23 062	-21 409	-17 309	-13 392	-27 258	-18 985	-23 066
Research and development costs	-30 863	-31 070	-30 588	-51 014	-27 126	-31 629	-26 173	-23 959
Other operating revenues and expenses	-670	255	468	-231	4 776	-245	-77	190
Operating income	20 472	33 426	18 993	-16 124	5 302	3 802	11 207	2 304
Financial income and expenses	67 207	-781	11 015	81 686	-4 348	7 638	5 358	447
Income after financial items	87 679	32 645	30 008	65 562	954	11 440	16 565	2 751
Taxes	-1 862	-5 452	-7 223	2 912	1 330	-4 554	-2 389	-2 017
Net income	85 817	27 193	22 785	68 474	2 284	6 886	14 176	734
Attributable to								
Parent Company's shareholders	85 817	27 193	22 785	68 474	2 284	6 886	14 176	734
Earnings per share, SEK	2.72	0.86	0.72	2.17	0.08	0.23	0.48	0.02
Earnings per share, SEK ¹⁾	2.71	0.86	0.72	2.17	0.08	0.23	0.48	0.02
Average number of outstanding shares	31 499 470	31 499 470	31 499 470	31 499 470	30 139 116	29 872 450	29 831 919	29 602 717
Average number of outstanding shares ¹⁾	31 685 836	31 617 251	31 499 470	31 499 470	30 139 116	29 872 450	29 831 919	29 602 717
Number of shares at closing day	31 499 470	31 499 470	31 499 470	31 499 470	31 499 470	29 899 470	29 831 919	29 831 919
Number of shares at closing day ¹⁾	31 685 836	31 617 251	31 499 470	31 499 470	31 499 470	29 899 470	29 831 919	29 831 919
EBITDA (Operating income before depreciation and amortization)	37 099	51 144	35 942	20 746	18 931	17 216	23 644	13 580
Depreciation and amortization on intangible assets	-8 732	-9 623	-9 313	-30 025	-7 725	-7 715	-7 633	-7 145
Depreciation and amortization on tangible assets	-7 895	-8 095	-7 636	-6 845	-5 904	-5 699	-4 804	-4 131
Operating income	20 472	33 426	18 993	-16 124	5 302	3 802	11 207	2 304

¹⁾ After dilution

Consolidated Statement of Total Comprehensive Income by quarter

SEK Thousands	Jul-Sep 2024	Apr-Jun 2024	Jan-Mar 2024	Oct-Dec 2023	Jul-Sep 2023	Apr-Jun 2023	Jan-Mar 2023	Oct-Dec 2022
Net income	85 817	27 193	22 785	68 474	2 284	6 886	14 176	734
Other comprehensive income								
Items that may be reclassified to the income statement:								
Exchange rate differences	-30 987	-7 120	34 770	-51 948	-10 520	32 690	2 881	-12 173
Total other comprehensive income	-30 987	-7 120	34 770	-51 948	-10 520	32 690	2 881	-12 173
Total comprehensive income	54 830	20 073	57 555	16 526	-8 236	39 576	17 057	-11 439
Attributable to								
Parent Company's shareholders	54 830	20 073	57 555	16 526	-8 236	39 576	17 057	-11 439

Consolidated Key Ratios

SEK Thousands	January-September	January-September	July-September	July-September	January-December
	2024	2023	2024	2023	2023
Gross margin, %	74	74	75	73	74
Gross margin disposables, %	80	80	81	80	81
EBIT, %	12	5	10	4	1
EBIT (adjusted), %	13	9	13	10	7
EBITDA, %	21	14	19	13	13
EBITDA (adjusted), %	22	18	21	19	17
Net margin, %	23	5	43	2	15
Equity/assets ratio, %	91	86	91	86	89
Income per share, SEK	4.31	0.78	2.72	0.08	3.07
Shareholders' equity per share, SEK	66.13	61.21	66.13	61.21	61.75
Share price on closing day, SEK	511	275	511	275	330
Market cap on closing day, MSEK	16 096	8 647	16 096	8 647	10 379

Condensed Income Statement for the Parent Company

SEK Thousands	January-September	January-September	July-September	July-September	January-December
	2024	2023	2024	2023	2023
Net sales	325 805	198 098	107 710	60 233	276 937
Cost of goods sold	-73 122	-48 902	-25 492	-17 637	-73 128
Gross income	252 683	149 196	82 218	42 596	203 809
Selling expenses	-60 666	-51 569	-19 347	-19 467	-69 418
Administrative expenses	-67 852	-50 681	-22 620	-13 432	-68 948
Research and development expenses	-64 787	-51 979	-22 275	-18 691	-92 793
Other operating revenues and expenses	-28	49	-682	-226	-503
Operating income	59 350	-4 984	17 294	-9 220	-27 853
Financial income and expenses	17 400	12 885	2 852	-2 644	25 149
Income after financial items	76 750	7 901	20 146	-11 864	-2 704
Taxes	-15 030	-1 963	-2 030	2 441	-2 360
Net income	61 720	5 938	18 116	-9 423	-5 064

The Parent Company has no items to be recognized in other comprehensive income and therefore no statement of comprehensive income has been presented. Depreciation/amortization during the period amounts to SEK 18,031 (14,727) thousand, of which SEK 5,700 (4,982) thousand in the quarter.

Condensed Balance Sheet for the Parent Company

SEK Thousands	240930	230930	231231
ASSETS			
Intangible fixed assets	543 842	412 288	484 519
Property, plant and equipment	46 200	13 126	23 040
Financial assets	845 109	980 922	809 240
Total non-current assets	1 435 151	1 406 336	1 316 799
Inventories	58 570	43 979	56 965
Current receivables	57 726	50 815	47 409
Cash and bank	324 931	491 229	447 778
Total current assets	441 227	586 023	552 152
Total assets	1 876 378	1 992 359	1 868 951
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	1 788 660	1 797 286	1 721 754
Provisions	2 852	2 023	2 258
Long-term non-interest-bearing liabilities	12 698	138 087	81 464
Short-term non-interest-bearing liabilities	72 168	54 963	63 475
Total shareholders' equity and liabilities	1 876 378	1 992 359	1 868 951

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, this 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 Corporate 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, to the accounting principles used for the preparation of the latest Annual Report.

Note 2. Financial instruments

The Group's financial assets and liabilities valued at amortized cost amounted to SEK 638 million (728) and SEK 146 million (142) 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 5.0 million (138.1) relating to contingent consideration linked to acquisitions. Contingent considerations are classified under level 3 in accordance with IFRS 13, and measured at fair value with changes recognized in the Income Statement. The calculation of fair value relating to financial liabilities under level 3 affected the Income Statement by SEK 59.4 million (-1.7) in the period and was recognized in financial items.

Financial liabilities measured at fair value

TSEK	240930	230930	231231
Opening balance	64 415	170 416	170 416
Discount of additional purchase considerations	4 760	-	751
Write-down of additional purchase considerations	-64 389	-4 157	-69 036
Payment of additional purchase considerations	-	-34 000	-34 003
Exchange-rate differences	214	5 828	-3 713
Closing balance	5 000	138 087	64 415

Note 3. Net sales

Distribution of net sales

SEK Thousands	January-September							Total consolidated	
	Thoracic		Abdominal		Services		2024	2023	
	2024	2023	2024	2023	2024	2023	2024	2023	
Disposables	391 687	274 888	110 430	85 490	-	-	502 117	360 378	
Machines	11 325	11 020	19 333	10 376	-	-	30 658	21 396	
Service	-	-	-	-	62 076	60 028	62 076	60 028	
Net sales	403 012	285 908	129 763	95 866	62 076	60 028	594 851	441 802	

SEK Thousands	July-September							Total consolidated	
	Thoracic		Abdominal		Services		2024	2023	
	2024	2023	2024	2023	2024	2023	2024	2023	
Disposables	133 071	89 833	33 702	30 821	-	-	166 773	120 654	
Machines	7 795	1 051	5 501	4 297	-	-	13 296	5 348	
Service	-	-	-	-	18 411	20 612	18 411	20 612	
Net sales	140 866	90 884	39 203	35 118	18 411	20 612	198 480	146 614	

Note 4. Consolidated operating segments

The Group's segments are Thoracic, Abdominal and Services. The segments correspond to the Group's business areas and are measured and monitored by XVIVO's management at a revenue and gross margin level.

SEK Thousands	January-September							
	Thoracic		Abdominal		Services		Total consolidated	
	2024	2023	2024	2023	2024	2023	2024	2023
Net sales	403 012	285 908	129 763	95 866	62 076	60 028	594 851	441 802
Cost of goods sold	-69 380	-47 425	-45 725	-33 754	-38 465	-32 746	-153 570	-113 925
Gross income	333 632	238 483	84 038	62 112	23 611	27 282	441 281	327 877
Gross margin (%)	83	83	65	65	38	45	74	74

SEK Thousands	July-September							
	Thoracic		Abdominal		Services		Total consolidated	
	2024	2023	2024	2023	2024	2023	2024	2023
Net sales	140 866	90 884	39 203	35 118	18 411	20 612	198 480	146 614
Cost of goods sold	-24 818	-13 240	-14 308	-13 401	-11 423	-12 375	-50 549	-39 016
Gross income	116 048	77 644	24 895	21 717	6 988	8 237	147 931	107 598
Gross margin (%)	82	85	64	62	38	40	75	73

Geographical areas

SEK Thousands	January-September							
	Thoracic		Abdominal		Services		Total consolidated	
	2024	2023	2024	2023	2024	2023	2024	2023
North America	283 019	177 112	17 336	6 237	62 076	60 028	362 431	243 377
South and Latin America	3 277	4 391	191	-	-	-	3 468	4 391
EMEA	91 360	72 630	106 858	87 629	-	-	198 218	160 259
Asia and Pacific	25 356	31 775	5 378	2 000	-	-	30 734	33 775
Net sales	403 012	285 908	129 763	95 866	62 076	60 028	594 851	441 802

SEK Thousands	July-September							
	Thoracic		Abdominal		Services		Total consolidated	
	2024	2023	2024	2023	2024	2023	2024	2023
North America	105 468	56 531	4 787	2 074	18 411	20 612	128 666	79 217
South and Latin America	1 398	718	191	-	-	-	1 589	718
EMEA	27 352	22 372	32 809	32 198	-	-	60 162	54 570
Asia and Pacific	6 648	11 263	1 415	846	-	-	8 063	12 109
Net sales	140 866	90 884	39 203	35 118	18 411	20 612	198 480	146 614

Note 5. Goodwill

	January-September	January-September	July-September	July-September	January-December
TSEK	2024	2023	2024	2023	2023
Opening balance	591 392	625 319	612 662	653 469	625 319
Reclassification to other intangible fixed assets	-	-	-	-	-28 174
Reclassification to deferred tax liability	-	-	-	-	5 804
Exchange-rate differences	6 248	20 090	-15 022	-8 060	-11 557
Closing balance	597 640	645 409	597 640	645 409	591 392

Reconciliation of alternative performance measures

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

EBITDA

SEK Thousands	January-September 2024	January-September 2023	July-September 2024	July-September 2023	January-December 2023
Operating income	72 891	20 311	20 472	5 302	4 187
Depreciation and amortization on intangible assets	27 668	23 073	8 732	7 725	53 098
Depreciation and amortization on tangible assets	23 626	16 407	7 895	5 904	23 252
EBITDA (Operating income before depreciation and amortization)	124 185	59 791	37 099	18 931	80 537

EBITDA (adjusted)

SEK Thousands	January-September 2024	January-September 2023	July-September 2024	July-September 2023	January-December 2023
EBITDA (Operating income before depreciation and amortization)	124 185	59 791	37 099	18 931	80 537
Acquisition costs	4 975	-	4 975	-	-
Integration costs	971	21 625	-3	9 055	22 103
EBITDA (adjusted)	130 131	81 416	42 071	27 986	102 640

EBIT (adjusted)

SEK Thousands	January-September 2024	January-September 2023	July-September 2024	July-September 2023	January-December 2023
EBIT (Operating income)	72 891	20 311	20 472	5 302	4 187
Acquisition costs	4 975	-	4 975	-	-
Integration costs	971	21 625	-3	9 055	22 103
Write-down of intangible asset	222	-	-	-	16 439
EBIT (adjusted)	79 059	41 936	25 444	14 357	42 729

Gross margin

SEK Thousands	January-September 2024	January-September 2023	July-September 2024	July-September 2023	January-December 2023
Operating income					
<i>Net sales</i>	594 851	441 802	198 480	146 614	597 542
Operating expenses					
<i>Cost of goods sold</i>	-153 570	-113 925	-50 549	-39 016	-152 431
Gross income	441 281	327 877	147 931	107 598	445 111
Gross margin %	74	74	75	73	74

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/Asset ratio

SEK Thousands	240930	230930	231231
Shareholders' equity	2 083 175	1 928 115	1 945 045
Total assets	2 278 193	2 237 108	2 195 610
Equity/assets ratio %	91	86	89

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 ratios	Definition	Purpose
Gross margin disposables, %	Gross profit for disposables during the period divided by net sales for disposables during the period.	The company believes that the key ratio provides an in-depth understanding of the company's profitability. Since the pricing strategy for machines differs from the pricing strategy from all other operations, the gross margin is presented separately for machines and disposables.
Gross margin, %	Gross profit for the period divided by net sales for the period.	The company believes that the key ratio provides an in-depth understanding of the company's profitability.
EBITDA margin, %	EBITDA (operating income before depreciation and amortization for the period) divided by 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 for the period) adjusted for items affecting comparability and divided by net sales for the period.	The company believes that the key ratio provides an in-depth understanding of the company's profitability. The company also considers that adjusted EBITDA provides a more true and fair view of the company's EBITDA for the core operations.
Adjusted EBIT margin, %	EBIT (operating income for the period) adjusted for items affecting comparability, divided by net sales for the period.	The company believes that the key ratio provides an in-depth understanding of the company's profitability. The company also considers that adjusted EBIT provides a more true and fair view of the company's EBIT for the core operations.
Operating margin, %	Operating income for the period divided by 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 for the period divided by 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 divided by total assets.	The ratio indicates what percentage of total assets consists of shareholders' equity and it has been included to help provide investors with 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 balance sheet 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 divided by the average number of 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 have evolved.
Earnings per share after dilution, SEK	Income for the period divided by the average number of 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 have evolved.
Organic growth	Organic growth refers to sales growth compared to the same period the previous year, adjusted for currency translation effects and acquisitions. Acquisitions are adjusted for by excluding net sales during the current year for acquisitions made during the current or previous year where the net sales relate to the period when the acquisition did not contribute to sales in both years. The effect of the acquisition of a distributor (like the acquisition of XVIVO S.r.l. in 2022) is adjusted for by deducting the distributor's margin that is added to Group sales as a result of the acquisition and recognizing it as acquired growth. Currency effects are calculated by recalculating the period's and previous period's sales in local currencies in SEK at the same exchange rate.	Organic growth enables comparison of net sales over time, excluding the impact of currency translation effects and acquisitions.

Glossary

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

DBD	Donation after brain death.
DCD	Donation after circulatory death.
DHOPE	Double hypothermic non-ischemic machine organ perfusion, i.e. cold oxygenated machine organ perfusion using double cannulation
Assessment	Assessment of the function of an organ.
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. The opposite of in vivo.
EVLP (Ex Vivo Lung Perfusion)	Perfusion of a lung outside the body. The procedure is normally carried out to evaluate a lung before transplantation.
FDA or US Food and Drug Administration	The FDA is the US 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 medical 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. A HDE is similar in both form and content to a Premarket Approval (PMA) application but is exempt from the efficacy requirements of a PMA.
HOPE	Hypothermic non-ischemic machine organ perfusion, i.e. cold oxygenated machine organ perfusion
IDE-application	An Investigational Device Exemption (IDE) is an application that must be submitted to receive the Food and Drug Administration's (FDA) approval to use a novel medical device in a clinical study.
Clinical study/trial	A study in healthy or sick people to examine the effect of a drug or treatment method.
Machine sales	Revenues from the sale or rental of machinery for mechanical perfusion and preservation of organs.
Machine perfusion	New technology that improves preservation and assessment 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 machines. 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.
NRP	Normothermic regional perfusion. Treatment method in DCD donation where organs are perfused in the donor.
OPO or Organ Procurement Organization	In the United States, an organ procurement organization (OPO) is a non-profit organization responsible for the assessment 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.
Pre-clinical 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 to enable 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.
Xenotransplantation	Transplantation of cells, tissues or organs from one species to another.
Other sales	The Other sales product category refers to revenues relating to freight, service and training.



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