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Heart transplant patient
Australia

Year-End Report 2024

XVIVO Perfusion AB (publ)

XVIVO

Year-End Report 2024

Fourth quarter 2024 (October 1 - December 31)

- Net sales amounted to SEK 227.6 million (155.7), corresponding to growth of 46 percent in SEK and 45 percent in local currencies. Organic growth accounted for 44 percent and acquired growth for 1 percent.
- All business areas delivered underlying organic growth adjusted for currency effects: Thoracic disposables 50 percent, Abdominal disposables 35 percent and Services 16 percent.
- Gross margin for disposables was 82 percent (81). The total gross margin increased to 77 percent (75).
- Operating income (EBIT) increased to SEK 15.5 million (-16.1) and includes a write-down of intangible assets of SEK -20.1 million (-16.4) related to discontinued development projects. Adjusted EBIT amounted to SEK 36.6 million (0.8).
- Operating income before depreciation and amortization (EBITDA) increased to SEK 51.9 million (20.7), corresponding to an EBITDA margin of 23 percent (13). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 52.9 million (21.2), corresponding to an adjusted EBITDA margin of 23 percent (14).
- Net profit amounted to SEK 36.4 million (68.5) and was impacted by financial expenses of SEK -0.4 million (73.7) attributable to fair value valuation of financial liabilities. Earnings per share amounted to SEK 1.16 (2.17).
- Cash flow from operating activities was SEK 62.1 million (18.1). Total cash flow amounted to SEK -51.7 million (-38.2) primarily impacted by investments in R&D projects, production facilities and the acquisition of FlowHawk.

Significant events in the quarter

- Enrollment of patients completed five months early in XVIVO's clinical trial in the US evaluating heart preservation technology
- Lena Hagman is appointed deputy CEO.

The period 2024 (January 1 - December 31)

- Net sales amounted to SEK 822.4 million (597.5), corresponding to growth of 38 percent in SEK and 39 percent in local currencies. Organic growth accounted for 39 percent, currency effect -1 percent.
- All business areas delivered underlying organic growth adjusted for currency effects: Thoracic disposables 46 percent, Abdominal disposables 32 percent and Services 7 percent.
- Gross margin for disposables was 81 percent (81). The total gross margin increased to 75 percent (74).
- Operating income (EBIT) increased to SEK 88.4 million (4.2) and includes a write-down of intangible assets of SEK -20.3 million (-16.4) related to discontinued development projects. Adjusted EBIT amounted to SEK 115.6 million (42.7).
- Operating income before depreciation and amortization (EBITDA) increased to SEK 176.1 million (80.5), corresponding to an EBITDA margin of 21 percent (13). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 183.1 million (102.6), corresponding to an adjusted EBITDA margin of 22 percent (17).
- Net profit increased to SEK 172.2 million (91.8) and was impacted by financial income of SEK 59.0 million (72.0) attributable to fair value valuation of financial liabilities. Earnings per share amounted to SEK 5.47 (3.07).
- Cash flow from operating activities increased to SEK 111.3 million (46.3). Total cash flow amounted to SEK -143.4 million (303.2) primarily impacted by investments in R&D projects, production facilities, and the acquisition of FlowHawk.

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.
- 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 to increase lung transplants in Sweden and Denmark
- Results of XVIVO's European heart preservation study published in The Lancet
- XVIVO signs agreement to acquire FlowHawk – a unique communication platform for the transplant process. The transaction was completed on October 11

Events after the end of the period

- IDE application filed with the FDA in the US for approval to start a clinical trial with Liver Assist
- XVIVO entered into a revolving credit facility of EUR 20 million

Key ratios

TSEK	January-December 2024	January-December 2023	October-December 2024	October-December 2023
Net sales	822 415	597 542	227 564	155 740
Gross margin, %	75	74	77	75
Gross margin disposables %	81	81	82	81
EBIT	88 353	4 187	15 462	-16 124
EBIT (adjusted) ¹⁾	115 633	42 729	36 574	793
EBITDA	176 069	80 537	51 884	20 746
EBITDA (adjusted) ²⁾	183 058	102 640	52 927	21 224
Cash flow from operating activities	111 290	46 288	62 084	18 128
Earnings per share, SEK	5.47	3.07	1.16	2.17
Changes in net sales				
Organic growth in local currency, %	39	30	44	12
Acquired growth, %	-	6	1	4
Currency effect, %	-1	8	1	2
Total growth, %	38	44	46	18

1) Adjusted for the effect of non-recurring costs of SEK -21.1 (-16.9) million for the quarter, and SEK -27.3 (-38.5) million for the period. For specification, see Reconciliation of alternative performance measures

2) Adjusted for the effect of non-recurring costs of SEK -1.0 (-0.5) million for the quarter, and SEK -7.0 (-22.1) million for the period. For specification, see Reconciliation of alternative performance measures.

A strong finish to 2024

XVIVO finished the year positively. Net sales in the fourth quarter reached a new record – SEK 228 million, corresponding to organic growth of 44 percent in local currency. All three business areas experienced double-digit growth and increased the customer base. Top line growth also translated to an improved adjusted EBITDA margin of 23 percent (14) and cashflow from operating activities of SEK 62 million (18). For the full year, net sales amounted to SEK 822 million, equivalent to an organic growth of 39 percent. Full year adjusted EBITDA was 22 percent (17).



Christoffer Rosenblad, CEO

During 2024 we estimate that more than 12,000 patients were given a lifesaving transplant using XVIVO's products or services. It has been a strong year for XVIVO, marked by topline growth and encouraging progress in clinical and regulatory activities. During the year, we have continued to invest in our organization to position ourselves for growth. In particular, our field force is expanding to meet the growing demand for our products and services. Despite investments, we have demonstrated scalability in sales, resulting in an increase in EBITDA.

The primary drivers of growth during the year have been EVLP in the US and liver perfusion in Europe. In the US, we have built a strong sales force that is fully trained and well-connected with transplant clinics and OPO:s. XVIVO has been the market leader within lung transplantation for many years, and in 2024, that position became even stronger: EVLP adoption increased among all US customers, and it is encouraging that three new clinics started XPS programs during the year.

For our heart technology there have been several important highlights this year. The 30-day follow-up data from our European trial, which included 202 patients, was published in August in *The Lancet*. Since Primary Graft Dysfunction (PGD) is the leading indicator of long-term survival, we were very pleased that the trial demonstrated a 76 percent risk reduction in severe PGD.

We are currently awaiting regulatory approval from the European authorities for our heart technology. All stakeholders are working diligently toward the common goal of achieving approval, but high-standard regulatory processes always take time. The regulatory file is currently handled by the European Medical Agency and the Swedish MPA. XVIVO is ready for a European launch as soon as we clear the two medical agencies and receive a CE-mark.

In the US, our heart trial reached a major milestone in November with the inclusion of the last patient—five months ahead of schedule. This reflects the strong enthusiasm and commitment from participating trial centers. Once we have the one-year follow-up data analyzed by the end of 2025, we will be ready to start the regulatory process with FDA.

In Europe, XVIVO continues to build on its market-leading position in liver perfusion. The Liver Assist technology, which celebrated its 25th anniversary in 2024, is the liver perfusion device with the most extensive clinical evidence on the market. One example is a groundbreaking study published in *The Lancet* in January 2024, demonstrating that Liver Assist enables extended liver

"During 2024 we estimate that more than 12,000 patients were given a lifesaving transplant using XVIVO's products or services"

perfusion times of up to 20 hours. During the year studies have also been published showing that the use of the Liver Assist improves graft survival, hospital economics as well as clinical team's work life balance.

In November, XVIVO hosted a Masterclass on Liver Transplantation in Belgium. Over the course of two days, 100 leading transplant surgeons from 16 countries gathered to exchange experiences and discuss the latest trends. The event was highly appreciated and further reinforced XVIVO's position as a European leader in liver perfusion.

Regarding kidney perfusion, our previous production capacity constraints have been resolved and no longer impact operations. In 2024, we also successfully continued laying the foundation of a European customer base, with the device now installed in more than 15 high volume hospitals. The clinical benefits for DCD kidneys transplanted after HOPE (Hypothermic Oxygenated Perfusion) are supported by strong evidence. In 2025, we will explore the potential benefits of HOPE for DBD kidneys as well. Such data will be key for Kidney Assist Transport to effectively address the entire kidney market in the US and in Europe.

Looking ahead to 2025, it promises to be an exciting year for XVIVO, with significant developments expected in several key areas.

For our heart technology, we initiated the European trial in 2019, and now, almost six years later, we are just months away from launching the technology in Europe. From the early stages, we believed that this technology would change the paradigm in heart preservation. Throughout our European clinical trial, along with several Investigator-Initiated Studies (IIS) and now the completed enrollment in the US trial, we are highly confident that the HOPE concept represents the best method for preserving a heart outside the body. In the US, with the trial now completed, the heart technology cannot be used until FDA approval is obtained. However, transplant centers can perform a limited number of transplants under the so-called Continuous Access Protocol, which is currently under FDA review

In 2025, we will sharpen our focus on our two core markets: North America and Europe. In Europe, the primary focus will be the launch of our heart technology together with growing our current business. In North America, the emphasis will be on further expanding our EVLP business and continuing to grow and strengthen our digital and organ recovery service offering. In 2025 we will continue to invest for the future. Our commercial and clinical organization will be built out and equipped to handle a broader product portfolio and we will invest further in building a tailored service offering that addresses evolving customer needs.

I have saved something exciting for last: our plan to bring our liver technology to the US market is progressing well. The IDE application, which requires approval from the FDA to initiate a clinical trial, has been submitted. We are hopeful for swift approval and aim to start the clinical trial in 2025.

As we look ahead, we remain committed to our vision that *'no one should die waiting for a new organ'*. We will continue to push the boundaries of organ transplantation and improve outcomes for patients worldwide. The achievements of the past year, combined with the exciting opportunities on the horizon, position XVIVO for rapid but sustained growth. None of this would be possible without the trust and enthusiasm of our customers and the dedication of our employees. Together, we are shaping the future of organ transplantation, and I am confident that 2025 will be another impactful year for XVIVO.

Christoffer Rosenblad, CEO

Significant research progress and important publications based on XVIVO technologies in 2024

Heart

Significant advancements in XVIVO-sponsored studies were achieved in 2024. A landmark publication in *The Lancet* reported findings from a large, randomized trial comparing donor heart preservation using XVIVO Heart Assist Transport (XHAT) with traditional static cold storage (ice). Results demonstrated a 61% reduction in early organ dysfunction among patients receiving XHAT-preserved donor hearts¹. Additionally, patient enrollment in the U.S. PRESERVE trial, an IDE study evaluating the safety and effectiveness of the XHAT system for FDA PMA approval, was completed five months ahead of schedule. In Europe, the first patients were enrolled in a multicenter feasibility trial investigating the use of XHAT for direct procurement of hearts from donation after circulatory death (DCD) donors.

Kidney

A 2024 Cochrane review summarized the evidence supporting use of kidney perfusion technologies, emphasizing the unique advantages of oxygenated organ perfusion, a proprietary feature of XVIVO's kidney device².

Lung

The use of ex vivo lung perfusion (EVLP) with XVIVO's XPS technology surged in 2024. A recent study highlighted the clinical value of real-time lung weight analysis during EVLP assessments, a feature available in the latest version of the XPS³. XVIVO continues to modernize long-established products, such as Perfadex Plus, which has been confirmed effective for static lung preservation at 10°C—a temperature increasingly preferred over traditional ice storage⁴.

Liver

Extensive clinical evidence, including randomized trials and a comprehensive Cochrane review, underscores the benefits of XVIVO's cold perfusion technology (HOPE) for liver transplantation. A 2024 study in *Transplantation* demonstrated an average cost reduction of EUR 25,800 per patient during the first year after liver transplantation when HOPE was used. The savings were attributed to shorter hospital stays, fewer complications, and improved outcomes⁵. Additional studies revealed that XVIVO's technology facilitates daytime liver transplants, benefiting both patients and surgical teams⁶. Long-term follow up from a randomized trial demonstrated that HOPE reduces late-onset morbidity and improves long-term graft survival⁷. In addition, a report involving 1200+ HOPE patients demonstrated excellent survival rates associated with XVIVO's liver technology, when 81% of patients receiving a liver after HOPE were alive 5 years after the transplant, despite a considerably proportion of high-risk donor livers transplant⁸. The 2023 Cochrane review summarizing all existing trial data on the use of HOPE in liver transplantation reported a 55% reduction in the risk of patient graft lost (complete loss of transplanted liver function) during the first year after transplant with HOPE, vs. organ storage on ice⁹.

¹ Rega F, et al. Hypothermic oxygenated perfusion of the donor heart in heart transplantation; the short-term outcome from a randomized, controlled, open-label, multicentre clinical trial. *Lancet*. 2024 Aug 17;404(10455):670-682.

² Tingle SJ, et al. Normothermic and hypothermic machine perfusion preservation versus static cold storage for deceased donor kidney transplantation. *Cochrane Database Syst Rev*. 2024 Jul 9;7(7)

³ Sakanoue I, et al., Real-time lung weight measurement during clinical ex vivo lung perfusion. *J Heart Lung Transplant*, 2024. 45(12): p. 2008-2017.

⁴ Gil Barturen, M, et al., Donor Lung Preservation at 10°C: Clinical and Logistical Impact. *Arch Bronconeumol*, 2024. 60(6): p. 536-545.

⁵ Endo, Chikako, et al. Cost-effectiveness of Dual Hypothermic Oxygenated Machine Perfusion Versus Static Cold Storage in DCD Liver Transplantation. *Transplantation* October 08, 2024

⁶ Brüggewirth IMA, et al. DHOPE-PRO Trial Investigators. Prolonged hypothermic machine perfusion enables daytime liver transplantation - an IDEAL stage 2 prospective clinical trial. *EClinicalMedicine*. 2024 Jan 5;68:102411.

⁷ Czigany Z, et al. Improved outcomes after hypothermic oxygenated machine perfusion in liver transplantation - Long-term follow-up of a multicenter randomized controlled trial. *Hepatal Commun*. 2024 Feb 5;8(2):e0376.

⁸ Eden J, et al. Long-term outcomes after hypothermic oxygenated machine perfusion and transplantation of 1,202 donor livers in a real-world setting (HOPE-REAL study). *J Hepatol*. 2025 Jan;82(1):97-106.

⁹ Tingle SJ, Dobbins JJ, Thompson ER, Figueiredo RS, Mahendran B, Pandanaboyana S, Wilson C. Machine perfusion in liver transplantation. *Cochrane Database Syst Rev*. 2025 Sep 12;9(9)

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

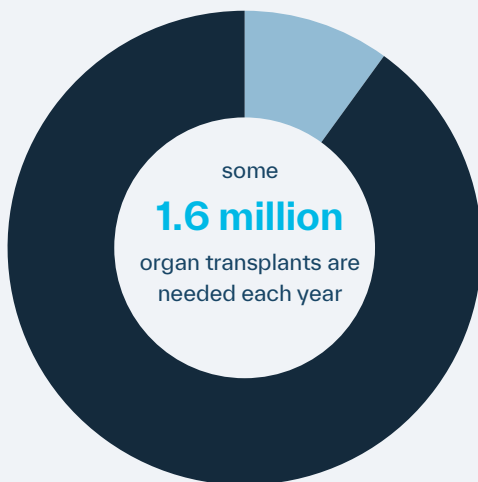
XVIVO's business concept is to develop and market effective, innovative technology for preserving, transporting and assessing organs outside the body while awaiting transplant, and to facilitate the transplant process by offering services in the form of organ recovery and organ perfusion.

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%

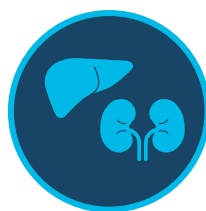
of total global demand
is met

XVIVO's offering increases
availability of transplantable
organs

Our business areas



Thoracic



Abdominal



Services

Compilation of net sales and EBITDA

SEK Thousands	January-December 2024	January-December 2023	October-December 2024	October-December 2023
Net Sales Thoracic	555 235	384 363	152 223	98 455
Net Sales Abdominal	179 420	134 039	49 657	38 173
Net Sales Services	87 760	79 140	25 684	19 112
Net Sales Total	822 415	597 542	227 564	155 740
Gross income Thoracic	463 597	321 877	129 965	83 394
Gross margin Thoracic, %	83%	84%	85%	85%
Gross income Abdominal	117 340	88 088	33 302	25 976
Gross margin Abdominal, %	65%	66%	67%	68%
Gross income Services	35 478	35 146	11 867	7 864
Gross margin Services, %	40%	44%	46%	41%
Gross income Total	616 415	445 111	175 134	117 234
Gross margin Total, %	75%	74%	77%	75%
Selling expenses	-283 982	-232 261	-80 983	-64 804
Administrative expenses	-95 788	-76 944	-22 865	-17 309
Research and development expenses	-148 329	-135 942	-55 808	-51 014
Other operating revenues and expenses	37	4 223	-16	-231
Operating Income	88 353	4 187	15 462	-16 124
Amortization and depreciation cost of goods sold	1 956	726	558	415
Amortization and depreciation selling expenses	24 828	19 000	6 743	9 746
Amortization and depreciation administrative expenses	5 181	4 447	1 351	1 220
Amortization, depreciation and write-down research and development expenses	55 751	52 177	27 770	25 489
EBITDA (Operating income before depreciation and amortization)	176 069	80 537	51 884	20 746
EBITDA, %	21%	13%	23%	13%
EBITDA (adjusted) 1)	183 058	102 640	52 927	21 224
EBITDA (adjusted), %	22%	17%	23%	14%

1) Adjusted for the effect of non-recurring costs of SEK -1.0 (-0.5) million for the quarter, and SEK -7.0 (-22.1) million for the period. For specification, see Reconciliation of alternative performance measures.

Summary

The quarter October - December 2024

Net sales and income

Net sales in the quarter amounted to SEK 227.6 million (155.7), an increase of 46 percent year-on-year, corresponding to organic growth of 44 percent. For a description of developments in each business area, see pages 14-16.

Total gross margin for the quarter was 77 percent (75). For comments regarding the margins in each business area, see pages 14-16.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 51.9 million (20.7), corresponding to an EBITDA margin of 23 percent (13). EBITDA was affected by acquisition and integration costs of SEK -1.0 million (-0.5). Adjusting for these items, EBITDA amounted to SEK 52.9 million (21.2), corresponding to an adjusted EBITDA margin of 23 percent (14).

Operating income (EBIT) amounted to SEK 15.5 million (-16.1). EBIT adjusted for the aforementioned costs and non-recurring write-downs linked to discontinued development projects amounted to SEK 36.6 million (0.8).

Selling expenses in relation to total sales amounted to 36 percent (42) in the quarter due to economies of scale from increased sales. R&D expenses amounted to 25 percent (33) of sales. Administrative expenses amounted to 10 percent (11) of sales. XVIVO will continue to invest in the organization, marketing activities and development over the coming years in order to meet the growing demand for products and services.

Net profit amounted to SEK 36.4 million (68.5) and was impacted by financial income and expenses of net SEK -0.4 million (73.7) attributable to fair value valuation of financial liabilities related to potential contingent considerations from acquisitions.

Capitalization and amortization

During the quarter, SEK 37.4 million (33.3) of development expenses were capitalized as intangible assets. The development expenses essentially related to expenses for R&D projects with the aim of obtaining regulatory approval in the US and Europe in heart and liver perfusion. Amortization of capitalized development expenditure amounted to SEK 4.8 million (7.2) in the quarter.

Cash flow

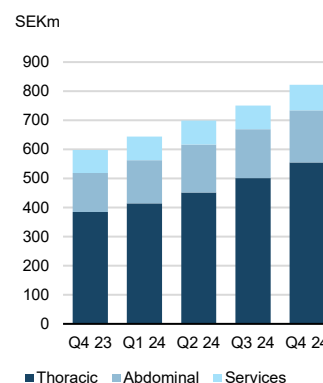
Cash flow from operating activities in the quarter amounted to SEK 62.1 million (18.1), positively affected by strong sales in the second half of the year and strengthened EBITDA due to economies of scale driven by strong sales.

Cash flow from investing activities amounted to SEK -111.4 million (-52.6), of which SEK -50.5 million (-) related to the acquisition of FlowHawk, SEK -38.4 million (-33.3) was invested in intangible assets, and SEK -22.2 million (-19.3) was invested in tangible assets.

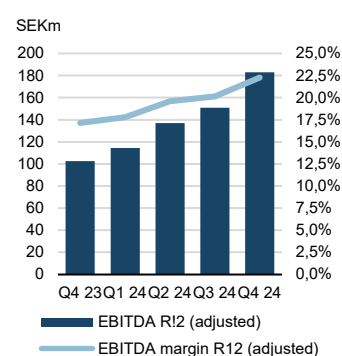
Cash flow from financing activities amounted to net SEK -2.4 million (-3.7). Exchange rate differences impacted the cash flow in the quarter by SEK 17.2 million (-10.0).

Cash and cash equivalents at the end of the quarter amounted to SEK 415.5 million (546.1).

Net sales by business area (R12)



EBITDA and EBITDA margin (adjusted, R12)



Significant events in the quarter

Enrollment of patients completed five months early in XVIVO's clinical trial in the US evaluating heart preservation technology

XVIVO's innovative heart technology is currently being tested in the US clinical trial "PRESERVE: A Prospective, Multi-center, Single-Arm, Open-Label Study of Hearts Transplanted after Non-Ischemic Heart PRESERVation from Extended Donors." This marks the recruitment completion of the Investigational Device Exemption (IDE) trial which was intended to enroll patients at an ambitious pace of 18 months, but was instead completed in 13 months – 5 months ahead of schedule. To date, 141 patients have undergone transplantation with the XVIVO heart technology at 14 leading heart transplant hospitals in the US. The next milestone will be one year follow-up, where patient outcomes will be collected and monitored. The results will be the foundation for XVIVO's application for regulatory approval from the US Food & Drug Administration (FDA) via the Pre-Market Approval (PMA) process.

Lena Hagman is appointed deputy CEO.

The Board of Directors of XVIVO Perfusion AB (publ) ("XVIVO") has appointed Lena Hagman as deputy CEO. Lena will also remain in her role as COO.

The period January - December 2024

Net sales and income

Sales in the period amounted to SEK 822.4 million (597.5), an increase of 38 percent year-on-year, equivalent to organic growth of 39 percent. For a description of developments in each business area, see pages 14-16.

The total gross margin for the period was 75 percent (74). For comments regarding the margins in each business area, see pages 14-16.

Operating income before depreciation and amortization (EBITDA) increased to SEK 176.1 million (80.5), corresponding to an EBITDA margin of 21 percent (13). EBITDA was affected by acquisition and integration costs of SEK -7.0 million (-22.1). Adjusting for these items, EBITDA amounted to SEK 183.1 million (102.6), corresponding to an adjusted EBITDA margin of 22 percent (17).

Operating income (EBIT) increased to SEK 88.4 million (4.2). EBIT adjusted for the aforementioned costs and non-recurring write-downs linked to discontinued development projects amounted to SEK 115.6 million (42.7).

Selling expenses as a proportion of total sales amounted to 35 percent (39) in the period. R&D expenses amounted to 18 percent (23) of sales. Administrative expenses amounted to 12 percent (13) of sales. XVIVO will continue to invest in the organization, marketing activities and development over the coming years in order to meet the growing demand for products and services.

Net profit amounted to SEK 172.2 million (91.8) and was impacted by financial income of net SEK 59.0 million (72.0) attributable to fair value valuation of financial liabilities related to potential contingent considerations from acquisitions. The item did not affect operating income (EBIT), EBITDA or cash flow.

Capitalization and amortization

During the period, SEK 119.9 million (100.1) 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 26.5 million (29.0) in the period.

Cash flow

Cash flow from operating activities increased to SEK 111.3 million (46.3) in the period. Cash flow from investing activities amounted to SEK -243.8 million (-161.6), of which SEK -50.5 million (-17.7) related to acquisition of FlowHawk, SEK -122.4 million (-100.9) was invested in intangible assets, and SEK -70.7 million (-43.0) was invested in tangible assets, such as production plant and perfusion machines. XVIVO will increase investments in intangible and tangible assets in 2025.

Cash flow from financing activities amounted to net SEK -10.9 million (418.5).

Cash and cash equivalents at the end of the period amounted to SEK 415.5 million (546.1).

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 90 percent (89) at the end of the period.

Net sales

**SEK
822
million**

Gross margin

75%

Adjusted EBITDA

22%

Significant events in the reporting period

Results from XVIVO's European heart preservation technology published in The Lancet

During the third 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 Lancet¹⁰. The trial compared outcomes for patients who received a donor heart preserved either on ice, the current standard method, or patients who received a donor heart preserved using XVIVO's Heart Assist Transport device. The primary outcome demonstrated a clinically important 44% lower risk of severe complications after transplantation when XVIVO's heart technology was implemented. The clinically important difference was driven by a significant 61% risk reduction for primary graft dysfunction (PGD). The study enrolled 204 patients from 15 transplantation clinics in 8 European countries.

First-ever transplantation of a donor heart transported across the Atlantic - made possible by 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 Lancet¹¹ in the first quarter of the year. After preservation outside the body for more than 12 hours a successful transplantation was performed in Paris - impossible with conventional methods but now made possible by the use of XVIVO's heart technology.

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. 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).

A recently published study in the Lancet¹² demonstrated that Liver Assist enables extended perfusion times of liver of up to 20 hours - improving the efficiency of hospital planning and logistics.

A 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). By extending perfusion times, UMCG in 2023 was able to perform the majority of all liver transplants during daytime rather than nighttime.

'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 enable preservation 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, and returned to, the University Hospital of Skåne in Lund, Sweden. This is the first collaboration in Europe that involves lungs transported over national borders.

XVIVO acquired FlowHawk - a unique communication platform for the transplant process

XVIVO has entered into an agreement to acquire a digital tool for communication and workflow developed for the transplant process, which includes the development and distribution of the FlowHawk software platform, from Healthtech Solutions Inc. trading as OmniLife. As part of the transaction, OmniLife's two co-founders, along with two sales representatives, will join XVIVO. The completion of the transaction took place on October 11, 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, financed using existing company funds. A contingent consideration 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. Non-recurring costs associated with the transaction amounted to SEK 5 million and impacted the third quarter of 2024. Integration of the operations is expected to be completed during the first half of 2025 with additional non-recurring costs of approximately SEK 5 million.

¹⁰ [https://doi.org/10.1016/S0140-6736\(24\)01078-X](https://doi.org/10.1016/S0140-6736(24)01078-X)

¹¹ [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)

¹² [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)

Financial income of SEK 59 million from fair value valuation of financial liabilities

Valuation of financial liabilities relating to contingent considerations for acquired businesses had a positive impact of SEK 59.0 million (72.0) on the Income Statement in the period. 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.

Significant events after the end of the period

IDE application filed with the FDA in the US to obtain approval to start a clinical trial with Liver Assist

An IDE (Investigational Device Exemption) application for a clinical trial with XVIVO's Liver Assist in the US, was submitted to the FDA for review in January. The aim is to generate the clinical data required to support a Pre-Market Approval (PMA) process as a route to commercialization. The study, entitled "DELIVER", is a Prospective, Single-Arm, Open-Label, Multi-Center Study. Livers from deceased donors transplanted after DHOPE (Dual hypothermic oxygenated perfusion) with XVIVO's Liver Assist. The proposed study includes 215 patients at up to 20 clinics in the US, with the primary endpoint being early allograft dysfunction on day 7 after transplantation, as well as patient survival with a functioning liver on postoperative day 180.

XVIVO enters into EUR 20 million revolving credit facility

XVIVO successfully entered into a revolving credit facility (RCF) of EUR 20 million. The facility can be drawn down in multiple currencies and has a term of three years. The credit facility provides XVIVO with further flexibility for strategic management of growth opportunities, financing working capital and general business purposes. The facility is provided by a leading Nordic bank.

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 (services within organ transplantation in the US). 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 market approval in all major markets. In heart transplantation, XVIVO's products are in a clinical study phase. Some sales in heart transplantation started in 2023-2024; 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-December 2024	January-December 2023	October-December 2024	October-December 2023
Net sales	555 235	384 363	152 223	98 455
Disposables	539 237	372 518	147 550	97 630
Machines	15 998	11 845	4 673	825
Gross margin, %	83	84	85	85
Disposables	85	85	87	85
Machines	34	39	41	60

The quarter October - December 2024

Thoracic presented another record quarter. Sales amounted to SEK 152.2 million (98.5), equivalent to growth of 55 percent year-on-year or 53 percent adjusted for currency effects. Sales of disposables delivered organic growth of 50 percent.

Machine perfusion accounted for 58 percent (53) of net sales. Growth was primarily driven by strong momentum for EVLP on the US market. Static preservation and other sales accounted for the remainder of net sales.

Gross margin for disposables was 87 percent (85).

The period January - December 2024

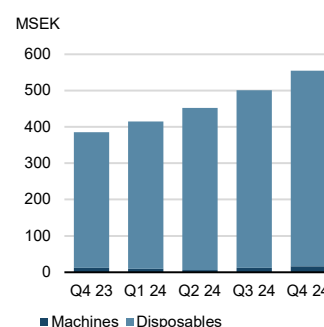
Sales increased by 44 percent in the period compared to the corresponding period in the previous year and amounted to SEK 555.2 million (384.4). The increase is equivalent to an increase of 45 percent adjusted for currency effects.

Sales of disposables increased by 45 percent and amounted to SEK 539.2 million (372.5).

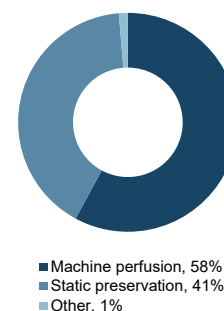
Organic growth amounted to 46 percent in local currencies. Machine perfusion accounted for 59 percent (50) of net sales. Static preservation and other sales accounted for the remainder of net sales.

Gross margin for disposables was 85 percent (85).

Net sales Thoracic (R12)



Net sales by product category Thoracic (Q4)



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-December 2024	January-December 2023	October-December 2024	October-December 2023
Net sales	179 420	134 039	49 657	38 173
Disposables	154 829	118 342	44 399	32 852
Machines	24 591	15 697	5 258	5 321
Gross margin, %	65	66	67	68
Disposables	65	66	67	69
Machines	69	67	70	65

The quarter October - December 2024

Sales amounted to SEK 49.7 million (38.2) in the quarter, which is equivalent to an increase of 30 percent year-on-year. Adjusted for currency effects, growth also totaled 30 percent. The increase for disposables totaled 35 percent, and also 35 percent adjusted for currency effects. The revenue was primarily generated in Europe, and approximately 71 percent related to liver perfusion.

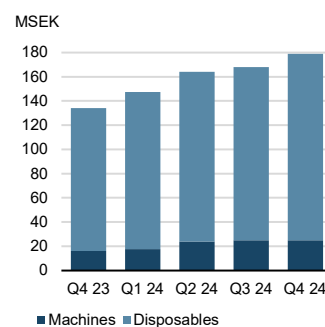
The gross margin for disposables was 67 percent (69). Margins are expected to improve at a pace with increased sales in the US and as we achieve economies of scale from new production facilities.

The period January - December 2024

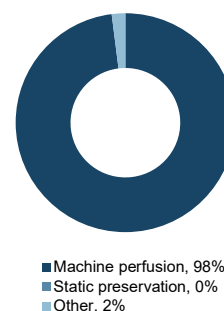
Sales in the period amounted to SEK 179.4 million (134.0), equivalent to growth of 34 percent year-on-year. Growth was 35 percent adjusted for exchange rate effects. The increase for disposables totaled 31 percent, or 32 percent adjusted for currency effects.

The gross margin for disposables was 65 percent (66).

Net sales Abdominal (R12)



Net sales by product category, Abdominal (Q4)



Services

The Services business area comprises XVIVO's organ recovery operations in the US in the area of donated hearts and lungs, and FlowHawk, a communication platform tailored for the transplant process. Organ recovery refers to the removal of organs from the donor body, preservation during transport, and coordination ahead of and during the recovery process.

Organic growth Q4

16%

Summary

SEK Thousands	January-December 2024	January-December 2023	October-December 2024	October-December 2023
Net sales	87 760	79 140	25 684	19 112
Gross margin, %	40	44	46	41

The quarter October - December 2024

Sales amounted to SEK 25.7 million (19.1), equivalent to an increase of 34 percent adjusted for currency effects. Organic growth accounted for 16 percent and acquired growth related to FlowHawk amounted to 18 percent.

Gross margin increased to 46 percent (41). Margins are expected to improve gradually as activity increases and new customer contracts are signed.




The period January - December 2024

Sales increased by 11 percent year-on-year, of which 4 percent related to acquired growth in relation to FlowHawk. Organ recovery's sales grew organically by 7 percent in year-on-year terms.

Gross margin amounted to 40 percent (44). Margins are expected to improve gradually as activity increases and new customer contracts are signed.

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 donated 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 final patient was enrolled in the study of XVIVO's heart technology in the US. The study will provide the basis for regulatory FDA approval. The fact that patient recruitment has progressed significantly faster than anticipated reflects the strong interest in the technology from transplant centers in the US.</p> <p>The results from XVIVO's European multicenter study were published in The Lancet during the third quarter, and attracted significant attention, as well as being presented at several scientific conferences. The benefit of preserving donated hearts with XVIVO's technology was reflected in a significant decrease in severe complications in the first 30 days after transplantation. During the quarter, additional patients have been recruited for the European study specifically investigating the outcomes of transplantation using DCD hearts preserved with XVIVO's technology.</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 summarized in an extensive Cochrane review in 2024. 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. The use of warm perfusion with XVIVO's technologies with the aim of evaluating liver function outside the body ahead of transplant has increased and 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).</p> <p>During the fourth quarter, a study was also published in the journal Transplantation, showing that the use of XVIVO's Liver Assist reduces the average cost per transplanted patient by EUR 25,800 in the first year after transplantation. The cost reduction is related to shorter hospital stays, fewer complications, and better outcomes for these patients.</p> <p>During the year, 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. 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>

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 170 employees, of whom 85 are women and 85 men. Of these, 54 are employed in Sweden and 116 outside Sweden. The head office is located in Gothenburg, Sweden and we have active subsidiaries in the US, Netherlands, Italy, France, Brazil and Australia. 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 and operational risks for the Group can be found in the Administration Report which is part of the Annual Report for 2023, available on the company's website www.xvivogroup.com.

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 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.

Dividend

The Board of Directors proposes that no dividend be paid for the 2024 financial year and that retained earnings be carried forward.

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 using 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.

We look forward to 2025, a year that will bring several important milestones, such as the commercialization of our heart technology in Europe and Australia/New Zealand, and the inclusion of the first patient in the liver study in the US. In addition, we will begin the production of disposable items in new production facilities that will ensure a future supply capacity for disposable items ten times higher than today. In terms of investments, we will continue to strengthen our commercial capacity in the US over the next year and invest to support the heart technology launch in Europe and Australia/New Zealand. We will also invest in establishing an organization in Canada, where we anticipate growth in 2026. The most important regulatory investments over the next two years will consist of the heart and liver PMA approval processes.

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 currently having a limited impact on XVIVO's operations both in terms of sales and the supply chain. 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.

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

Mölnådal, January 28, 2025

Gösta Johannesson
Chairman of the Board

Camilla Öberg
Board member

Göran Dellgren
Board member

Erik Strömqvist
Board member

Lars Henriksson
Board member

Lena Höglund
Board member

Christoffer Rosenblad
CEO

This Year-End Report has not 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 January 28, 2025 at 7.30 am CET.



Financial calendar

- 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
- Year-End Report 2025: Tuesday, January 27, 2026



Conference call

CEO Christoffer Rosenblad and CFO Kristoffer Nordström will present the Year-End Report in a conference call at 2.00 p.m. CET on Tuesday, January 28.
For access via conference call, click [here](#)
For access via webcast, click [here](#)



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Financial statements

Condensed Consolidated Statement of Net Income

SEK Thousands	January-December 2024	January-December 2023	October-December 2024	October-December 2023
Net sales	822 415	597 542	227 564	155 740
Cost of goods sold	-206 000	-152 431	-52 430	-38 506
Gross income	616 415	445 111	175 134	117 234
Selling expenses	-283 982	-232 261	-80 983	-64 804
Administrative expenses	-95 788	-76 944	-22 865	-17 309
Research and development expenses	-148 329	-135 942	-55 808	-51 014
Other operating revenues and expenses	37	4 223	-16	-231
Operating income	88 353	4 187	15 462	-16 124
Financial income and expenses	111 595	90 334	34 154	81 686
Income after financial items	199 948	94 521	49 616	65 562
Taxes	-27 766	-2 701	-13 229	2 912
Net income	172 182	91 820	36 387	68 474
Attributable to				
Parent Company's shareholders	172 182	91 820	36 387	68 474
Earnings per share, SEK	5.47	3.07	1.16	2.17
Earnings per share, SEK ¹⁾	5.44	3.07	1.15	2.17
Average number of outstanding shares	31 499 470	29 935 147	31 499 470	31 499 470
Average number of outstanding shares ¹⁾	31 650 106	29 935 147	31 650 106	31 499 470
Number of shares at closing day	31 499 470	31 499 470	31 499 470	31 499 470
Number of shares at closing day ¹⁾	31 650 106	31 499 470	31 650 106	31 499 470
EBITDA (Operating income before depreciation and amortization)	176 069	80 537	51 884	20 746
Depreciation and amortization on intangible assets	-55 273	-53 098	-27 605	-30 025
Depreciation and amortization on tangible assets	-32 443	-23 252	-8 817	-6 845
Operating income	88 353	4 187	15 462	-16 124

¹⁾ After dilution

Consolidated Statement of Total Comprehensive Income

SEK Thousands	January-December 2024	January-December 2023	October-December 2024	October-December 2023
Net income	172 182	91 820	36 387	68 474
Other comprehensive income				
Items that may be reclassified to the income statement				
Exchange rate differences	31 303	-26 897	34 640	-51 948
Total other comprehensive income	31 303	-26 897	34 640	-51 948
Total comprehensive income	203 485	64 923	71 027	16 526
Attributable to				
Parent Company's shareholders	203 485	64 923	71 027	16 526

Condensed Consolidated Statement of Financial Position

SEK Thousands	241231	231231
ASSETS		
Goodwill	682 483	591 392
Capitalized development expenditure	676 092	598 505
Other intangible fixed assets	48 704	30 461
Fixed assets	149 036	97 552
Financial assets	33 352	51 295
Total non-current assets	1 589 667	1 369 205
Inventories	227 406	141 604
Current receivables	170 149	138 713
Liquid funds	415 521	546 088
Total current assets	813 076	826 405
Total assets	2 402 743	2 195 610
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity, attributable to the Parent Company's shareholders	2 156 778	1 945 045
Long-term interest-bearing liabilities	23 126	21 169
Long-term non-interest-bearing liabilities	45 329	94 908
Short-term interest-bearing liabilities	10 917	10 268
Short-term non-interest-bearing liabilities	166 593	124 220
Total shareholders' equity and liabilities	2 402 743	2 195 610

Condensed Consolidated Cash Flow Statement

	January-December 2024	January-December 2023	October-December 2024	October-December 2023
Income after financial items	199 948	94 521	49 616	65 562
Adjustment for items not affecting cash flow	741	-1 992	12 740	-33 945
Paid taxes	-10 284	-7 017	-2 791	-3 652
Change in inventories	-77 515	-33 481	-31 997	660
Change in trade receivables	-17 772	-25 034	27 299	-11 987
Change in trade payables	16 172	19 291	7 217	1 490
Cash flow from operating activities	111 290	46 288	62 084	18 128
Cash flow from investing activities	-243 814	-161 619	-111 396	-52 585
Cash flow from financing activities	-10 902	418 547	-2 394	-3 726
Cash flow for the period	-143 426	303 216	-51 706	-38 183
Liquid funds at beginning of period	546 088	246 545	449 982	594 261
Exchange rate difference in liquid funds	12 859	-3 673	17 245	-9 990
Liquid funds at end of period	415 521	546 088	415 521	546 088

Consolidated Changes in Shareholders' Equity

SEK Thousands	Attributable to Parent Company's shareholders				
	Share capital	Other paid in capital	Reserves	Retained earnings incl. profit for the year	Sum shareholders' equity
Shareholders' equity as of January 1, 2023	762	1 313 839	87 781	27 754	1 430 136
Total comprehensive income January - December 2023	-	-	-26 897	91 820	64 923
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	43	447 540	-	-	447 583
Accounting effect of incentive programs according to IFRS 2	-	2 403	-	-	2 403
Shareholders' equity as of December 31, 2023	805	1 763 782	60 884	119 574	1 945 045
Total comprehensive income January - December 2024	-	-	31 303	172 182	203 485
Accounting effect of incentive programs according to IFRS 2	-	8 248	-	-	8 248
Shareholders' equity as of December 31, 2024	805	1 772 030	92 187	291 756	2 156 778

Condensed Consolidated Statement of Net Income by quarter

SEK Thousands	Oct-Dec 2024	Jul-Sep 2024	Apr-Jun 2024	Jan-Mar 2024	Oct-Dec 2023	Jul-Sep 2023	Apr-Jun 2023	Jan-Mar 2023
Net sales	227 564	198 480	210 349	186 022	155 740	146 614	154 573	140 615
Cost of goods sold	-52 430	-50 549	-52 105	-50 916	-38 506	-39 016	-39 111	-35 798
Gross income	175 134	147 931	158 244	135 106	117 234	107 598	115 462	104 817
Selling expenses	-80 983	-67 474	-70 941	-64 584	-64 804	-66 554	-52 528	-48 375
Administrative expenses	-22 865	-28 452	-23 062	-21 409	-17 309	-13 392	-27 258	-18 985
Research and development costs	-55 808	-30 863	-31 070	-30 588	-51 014	-27 126	-31 629	-26 173
Other operating revenues and expenses	-16	-670	255	468	-231	4 776	-245	-77
Operating income	15 462	20 472	33 426	18 993	-16 124	5 302	3 802	11 207
Financial income and expenses	34 154	67 207	-781	11 015	81 686	-4 348	7 638	5 358
Income after financial items	49 616	87 679	32 645	30 008	65 562	954	11 440	16 565
Taxes	-13 229	-1 862	-5 452	-7 223	2 912	1 330	-4 554	-2 389
Net income	36 387	85 817	27 193	22 785	68 474	2 284	6 886	14 176
Attributable to								
Parent Company's shareholders	36 387	85 817	27 193	22 785	68 474	2 284	6 886	14 176
Earnings per share, SEK	1.16	2.72	0.86	0.72	2.17	0.08	0.23	0.48
Earnings per share, SEK ¹⁾	1.15	2.71	0.86	0.72	2.17	0.08	0.23	0.48
Average number of outstanding shares	31 499 470	31 499 470	31 499 470	31 499 470	31 499 470	30 139 116	29 872 450	29 831 919
Average number of outstanding shares ¹⁾	31 650 106	31 685 836	31 617 251	31 499 470	31 499 470	30 139 116	29 872 450	29 831 919
Number of shares at closing day	31 499 470	31 499 470	31 499 470	31 499 470	31 499 470	31 499 470	29 899 470	29 831 919
Number of shares at closing day ¹⁾	31 650 106	31 685 836	31 617 251	31 499 470	31 499 470	31 499 470	29 899 470	29 831 919
EBITDA (Operating income before depreciation and amortization)	51 884	37 099	51 144	35 942	20 746	18 931	17 216	23 644
Depreciation and amortization on intangible assets	-27 605	-8 732	-9 623	-9 313	-30 025	-7 725	-7 715	-7 633
Depreciation and amortization on tangible assets	-8 817	-7 895	-8 095	-7 636	-6 845	-5 904	-5 699	-4 804
Operating income	15 462	20 472	33 426	18 993	-16 124	5 302	3 802	11 207

¹⁾ After dilution

Consolidated Statement of Total Comprehensive Income by quarter

SEK Thousands	Oct-Dec 2024	Jul-Sep 2024	Apr-Jun 2024	Jan-Mar 2024	Oct-Dec 2023	Jul-Sep 2023	Apr-Jun 2023	Jan-Mar 2023
Net income	36 387	85 817	27 193	22 785	68 474	2 284	6 886	14 176
Other comprehensive income								
Items that may be reclassified to the income statement:								
Exchange rate differences	34 640	-30 987	-7 120	34 770	-51 948	-10 520	32 690	2 881
Total other comprehensive income	34 640	-30 987	-7 120	34 770	-51 948	-10 520	32 690	2 881
Total comprehensive income	71 027	54 830	20 073	57 555	16 526	-8 236	39 576	17 057
Attributable to								
Parent Company's shareholders	71 027	54 830	20 073	57 555	16 526	-8 236	39 576	17 057

Consolidated Key Ratios

SEK Thousands	January-December	January-December	October-December	October-December
	2024	2023	2024	2023
Gross margin, %	75	74	77	75
Gross margin disposables, %	81	81	82	81
EBIT, %	11	1	7	-10
EBIT (adjusted), %	14	7	16	1
EBITDA, %	21	13	23	13
EBITDA (adjusted), %	22	17	23	14
Net margin, %	21	15	16	44
Equity/assets ratio, %	90	89	90	89
Income per share, SEK	5.47	3.07	1.16	2.17
Shareholders' equity per share, SEK	68.47	61.75	68.47	61.75
Share price on closing day, SEK	489	330	489	330
Market cap on closing day, MSEK	15 403	10 379	15 403	10 379

Condensed Income Statement for the Parent Company

SEK Thousands	January-December	January-December	October-December	October-December
	2024	2023	2024	2023
Net sales	453 072	276 937	127 267	78 839
Cost of goods sold	-98 081	-73 128	-24 959	-24 226
Gross income	354 991	203 809	102 308	54 613
Selling expenses	-84 074	-69 418	-23 408	-17 849
Administrative expenses	-100 459	-68 948	-32 607	-18 267
Research and development expenses	-105 605	-92 793	-40 818	-40 814
Other operating revenues and expenses	5 058	-503	5 086	-552
Operating income	69 911	-27 853	10 561	-22 869
Financial income and expenses	53 526	25 149	36 126	12 264
Income after financial items	123 437	-2 704	46 687	-10 605
Taxes	-24 872	-2 360	-9 842	-397
Net income	98 565	-5 064	36 845	-11 002

The Parent Company has no items to be recognized in other comprehensive income and therefore no statement of comprehensive income has been presented. Depreciation and amortization during the period amounted to SEK 42,075 (37,187) thousand, of which SEK 24,044 (22,460) thousand in the quarter.

Condensed Balance Sheet for the Parent Company

SEK Thousands	241231	231231
ASSETS		
Intangible fixed assets	554 548	484 519
Fixed assets	58 105	23 040
Financial assets	904 218	809 240
Total non-current assets	1 516 871	1 316 799
Inventories	75 751	56 965
Current receivables	62 811	47 409
Cash and bank	270 882	447 778
Total current assets	409 444	552 152
Total assets	1 926 315	1 868 951
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity	1 828 078	1 721 754
Provisions	3 014	2 258
Long-term non-interest-bearing liabilities	12 698	81 464
Short-term non-interest-bearing liabilities	82 525	63 475
Total shareholders' equity and liabilities	1 926 315	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 586 million (685) and SEK 172 million (134) 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 5.4 million (64.4) 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 59.0 million (72.0) in the period and was recognized in financial items.

Financial liabilities measured at fair value

TSEK	241231	231231
Opening balance	64 415	170 416
Revaluation of additional purchase considerations	-58 967	-71 998
Payment of additional purchase considerations	-	-34 003
Closing balance	5 448	64 415

Note 3. Net sales

Distribution of net sales

SEK Thousands	January-December						Total consolidated	
	Thoracic		Abdominal		Services		2024	2023
	2024	2023	2024	2023	2024	2023	2024	2023
Disposables	539 237	372 518	154 829	118 342	-	-	694 066	490 860
Machines	15 998	11 845	24 591	15 697	-	-	40 589	27 542
Service	-	-	-	-	87 760	79 140	87 760	79 140
Net sales	555 235	384 363	179 420	134 039	87 760	79 140	822 415	597 542

SEK Thousands	October-December						Total consolidated	
	Thoracic		Abdominal		Services		2024	2023
	2024	2023	2024	2023	2024	2023	2024	2023
Disposables	147 550	97 630	44 399	32 852	-	-	191 949	130 482
Machines	4 673	825	5 258	5 321	-	-	9 931	6 146
Service	-	-	-	-	25 684	19 112	25 684	19 112
Net sales	152 223	98 455	49 657	38 173	25 684	19 112	227 564	155 740

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-December							
	Thoracic		Abdominal		Services		Total consolidated	
	2024	2023	2024	2023	2024	2023	2024	2023
Net sales	555 235	384 363	179 420	134 039	87 760	79 140	822 415	597 542
Cost of goods sold	-91 638	-62 486	-62 080	-45 951	-52 282	-43 994	-206 000	-152 431
Gross income	463 597	321 877	117 340	88 088	35 478	35 146	616 415	445 111
Gross margin (%)	83	84	65	66	40	44	75	74

SEK Thousands	October-December							
	Thoracic		Abdominal		Services		Total consolidated	
	2024	2023	2024	2023	2024	2023	2024	2023
Net sales	152 223	98 455	49 657	38 173	25 684	19 112	227 564	155 740
Cost of goods sold	-22 258	-15 061	-16 355	-12 197	-13 817	-11 248	-52 430	-38 506
Gross income	129 965	83 394	33 302	25 976	11 867	7 864	175 134	117 234
Gross margin (%)	85	85	67	68	46	41	77	75

Geographical areas

SEK Thousands	January-December							
	Thoracic		Abdominal		Services		Total consolidated	
	2024	2023	2024	2023	2024	2023	2024	2023
North America	387 030	236 827	27 020	11 787	87 760	79 140	501 810	327 754
South and Latin America	5 828	5 729	191	239	-	-	6 019	5 968
EMEA	125 467	102 363	145 788	119 282	-	-	271 255	221 645
Asia and Pacific	36 910	39 444	6 421	2 731	-	-	43 331	42 175
Net sales	555 235	384 363	179 420	134 039	87 760	79 140	822 415	597 542

SEK Thousands	October-December							
	Thoracic		Abdominal		Services		Total consolidated	
	2024	2023	2024	2023	2024	2023	2024	2023
North America	104 011	59 715	9 684	5 550	25 684	19 112	139 379	84 377
South and Latin America	2 551	1 338	-	239	-	-	2 551	1 577
EMEA	34 107	29 733	38 930	31 653	-	-	73 037	61 386
Asia and Pacific	11 554	7 669	1 043	731	-	-	12 597	8 400
Net sales	152 223	98 455	49 657	38 173	25 684	19 112	227 564	155 740

Note 5. Goodwill

TSEK	January-December	January-December	October-December	October-December
	2024	2023	2024	2023
Opening balance	591 392	625 319	597 640	645 409
Acquired goodwill	56 630	-	56 630	-
Reclassification to other intangible fixed assets	-	-28 174	-	-28 174
Reclassification to deferred tax liability	-	5 804	-	5 804
Exchange-rate differences	34 461	-11 557	28 213	-31 647
Closing balance	682 483	591 392	682 483	591 392

Note 6. Business acquisitions

On October 11, 2024, new start-up XVIVO Digital Services Inc. acquired a digital tool for communication and workflow developed for the transplant process, which includes the development and distribution of the FlowHawk software platform, from Healthtech Solutions Inc. trading as OmniLife.

The acquisition analysis was completed as of December 31, 2024. Customer relationships valued at SEK 6 million and software valued at SEK 18 million have been identified in the acquisition, which are assessed to have an economic lifespan and depreciation period of 7 years. Goodwill amounts to SEK 57 million. Goodwill primarily consists of synergy effects that do not meet the requirements for accounting as intangible assets at the time of the acquisition. Primary synergies are potentially increased sales values per customer as well as increased sales potential for new customers, which can be achieved by utilizing XVIVO's knowledge and experience in marketing and established networks for the acquired operations. Synergies that could create future sales values are also to be found in development of, in particular, information and product development.

In the period after the acquisition, XVIVO Digital Services Inc. contributed SEK 3.3 million to Group revenue and adjusted for integration costs, SEK -1.8 million to Group net profit/loss in 2024. Net profit was affected by amortization costs of intangible assets identified in the acquisition analysis amounting to SEK 0.8 million. If the acquisition had taken place on January 1, 2024, this acquisition would have had a total effect on Group revenue of SEK 14.4 million and profit for the year of SEK -0.9 million, adjusted for integration costs and non-asset-related expenses.

The table below presents the final acquisition analysis.

SEK Thousands	Fair Value
Purchase price	
Paid purchase price	52 098
Hold-back	13 132
Contingent consideration	9 832
Total	75 063
Acquired net assets	
Intangible assets	23 646
Accounts receivable and other receivables	5 565
Accounts payable and other payables	-10 778
Fair value of acquired net assets	18 433
Goodwill	56 630
Total	75 063
Impact on the Group's cash flow	
Purchase price, initial payment in cash	52 098
Exchange-rate differences	-1 639
Impact on the Group's cash and cash equivalents	50 459

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

	January-December 2024	January-December 2023	October-December 2024	October-December 2023
SEK Thousands				
Operating income	88 353	4 187	15 462	-16 124
Depreciation and amortization on intangible assets	55 273	53 098	27 605	30 025
Depreciation and amortization on tangible assets	32 443	23 252	8 817	6 845
EBITDA (Operating income before depreciation and amortization)	176 069	80 537	51 884	20 746

EBITDA (adjusted)

	January-December 2024	January-December 2023	October-December 2024	October-December 2023
SEK Thousands				
EBITDA (Operating income before depreciation and amortization)	176 069	80 537	51 884	20 746
Acquisition costs	5 559	-	584	-
Integration costs	1 430	22 103	459	478
EBITDA (adjusted)	183 058	102 640	52 927	21 224

EBIT (adjusted)

	January-December 2024	January-December 2023	October-December 2024	October-December 2023
SEK Thousands				
EBIT (Operating income)	88 353	4 187	15 462	-16 124
Acquisition costs	5 559	-	584	-
Integration costs	1 430	22 103	459	478
Write-down of intangible asset	20 291	16 439	20 069	16 439
EBIT (adjusted)	115 633	42 729	36 574	793

Gross margin

	January-December 2024	January-December 2023	October-December 2024	October-December 2023
SEK Thousands				
Operating income				
<i>Net sales</i>	822 415	597 542	227 564	155 740
Operating expenses				
<i>Cost of goods sold</i>	-206 000	-152 431	-52 430	-38 506
Gross income	616 415	445 111	175 134	117 234
Gross margin %	75	74	77	75

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		241231	231231
Shareholders' equity		2 156 778	1 945 045
Total assets		2 402 743	2 181 091
Equity/assets ratio %		90	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. 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 assess 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 US 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 US, 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 US.
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 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 US, 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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