Interim report January-September 2023

XVIVO Perfusion AB (publ)

XVIVO Interim report January-September 2023

Third quarter 2023 (July 1 - September 30)

- Net sales amounted to SEK 146.6 million (96.8), corresponding to an increase of 51 percent in SEK and 42 percent in local currencies. Organic growth accounted for 37 percent and acquired growth for 5 percent.
- All business areas delivered underlying organic growth adjusted for currency effects: Thoracic disposables 23 percent, Abdominal disposables 100 percent and Services 68 percent.
- The gross margin for disposables increased to 80 percent (79). The total gross margin was 73 percent (72).
- Operating income (EBIT) amounted to SEK 5.3 million (-4.7). Adjusted EBIT amounted to SEK 14.4 million (-0.7).
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 18.9 million (5.9), corresponding to an EBITDA margin of 13 percent (6). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 28.0 million (9.9), corresponding to an adjusted EBITDA margin of 19 percent (10).
- Net profit amounted to SEK 2.3 million (5.4). Earnings per share amounted to SEK 0.08 (0.18).
- Cash flow from operating activities increased to SEK 24.8 million (17.0), primarily due to strong operating income before depreciation and amortization. Total cash flow amounted to SEK 424.4 million (-18.4), mainly comprising net proceeds from a new issue of SEK 440 million, and investments in R&D projects totaling SEK -21.5 million (-27.9).

Significant events during the quarter

- A directed share issue raised SEK 440 million before transaction costs
 and was completed with no discount
- US FDA grants XVIVO approval to include DCD hearts in IDE Clinical Trial
- XVIVO's heart preservation technology was used in a second successful xenotransplant (heart from pig to human)
- Strategic collaboration with MTJ Aviation aimed at strengthening XVIVO's service for organ retrieval in the US
- Further patient inclusion in the PrimECC study concluded Study data will be analyzed and strategic opportunities evaluated

The period 2023 (January 1 - September 30)

- Net sales amounted to SEK 441.8 million (283.8), corresponding to an increase of 56 percent in SEK and 45 percent in local currencies. Organic growth accounted for 39 percent and acquired growth for 6 percent.
- All business areas delivered underlying organic growth adjusted for currency effects: Thoracic disposables 34 percent, Abdominal disposables 71 percent and Services 75 percent.
- Gross margin for disposables increased to 80 percent (79). The total gross margin was 74 percent (71).
- Operating income (EBIT) amounted to SEK 20.3 million (4.1). Adjusted operating income (EBIT) amounted to SEK 41.9 million (5.7).
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 59.8 million (35.0), corresponding to an EBITDA margin of 14 percent (12). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 81.4 million (36.6), corresponding to an adjusted EBITDA margin of 18 percent (13).
- Net profit increased to SEK 23.3 million (17.7). Earnings per share amounted to SEK 0.78 (0.60).
- Cash flow from operating activities was SEK 28.2 million (6.1). Total cash flow amounted to SEK 341.4 million (-118.5), primarily comprising net proceeds from a new issue totaling SEK 440 million, payment of contingent consideration from the acquisition of Avionord (XVIVO S.r.l.) of SEK -10.9 million, the final part payment of the initial purchase consideration regarding the acquisition of STAR Teams of SEK -6.8 million and investments in R&D projects of SEK -66.9 million (-85.4).

Significant events in the reporting period

- Successful integration of Avionord M&P
- A pre-clinical study published in The Journal of Heart and Lung Transplantation demonstrated advantages associated with XVIVO's heart preservation technology, even in DCD donations
- Significant interest in XVIVO's heart technology in Australia and New Zealand. Approximately 30 percent of these countries' heart transplants were performed using our technology in the period
- A large multicenter study published in The Journal of Hepathology demonstrated improved evidence for the advantages of oxygenation cold perfusion of liver in donation after brain death (DBD)
- IDE application for XVIVO's heart preservation technology was approved by the US $\ensuremath{\mathsf{FDA}}$
- Patient inclusion completed in European clinical trial using heart
 preservation technology
- US service offering strengthened by commercial integration of STAR Teams
- During the period, the number of shares and votes in XVIVO Perfusion AB (publ) has increased by 1,667,551. As of September 30, 2023, there were a total of 31,499,470 shares and votes.

Significant events after the end of the period

· First transplant completed in the US heart preservation trial

Key ratios

тѕек	January- September 2023		July-September 2023	July-September 2022	Full year 2022
Net sales	441 802	283 778	146 614	96 835	415 292
Gross margin, %	74	71	73	72	72
Gross margin disposables %	80	79	80	79	79
EBIT	20 311	4 105	5 302	-4 657	6 409
EBIT (adjusted) ¹⁾	41 936	5 744	14 357	-653	14 285
EBITDA	59 791	34 996	18 931	5 904	48 576
EBITDA (adjusted) ¹⁾	81 416	36 635	27 986	9 908	56 452
Cash flow from operating activities	28 160	6 067	24 840	16 971	27 856
Earnings per share, SEK	0.78	0.60	0.08	0.18	0.62
Changes in net sales					
Organic growth in local currency, %	39	32	37	35	30
Acquired growth, %	6	18	5	22	15
Currency effect, %	11	14	9	19	16
Total growth, %	56	64	51	76	61

1) Adjusted for effect from costs attributable to business integration. Net adjustment totals SEK -9.1 (-4.0, which related to acquisition costs) million for the quarter. Net adjustment for the period totals SEK -21.6 (-1.6, which consisted of a reversal of a provision for cash-based incentive program for employees outside Sweden of SEK 6.3 million, integration costs of SEK -3.9 million and acquisition costs of SEK -4.0 million) million.

Successful capital raising and sharp focus on delivery

The company's growth in the first half-year continued into the third quarter, driven by increased use of machine perfusion. We completed a successful capital raising in the quarter, raising SEK 440 million before transaction costs. The strong support from our shareholders means that we are now ready to deliver on our strategy to achieve market leadership in all organs.



Christoffer Rosenblad, CEO

Total sales in the quarter amounted to SEK 147 million (97), equivalent to growth of 51 percent. Organic growth accounted for 37 percent and acquired growth amounted to 5 percent. The remaining growth related to currency effects.

Sales in the **Thoracic** business area amounted to SEK 91 million (71), an increase of 28 percent year-on-year and an increase of 20 percent adjusted for currency effects. Disposables delivered organic growth of 23 percent. Market growth and increased use of EVLP (Ex Vivo Lung Perfusion) remain the primary growth factors, with favorable progress in both the US and Europe.

Abdominal delivered another strong quarter, primarily driven by continued positive sales growth for liver perfusion in Europe. Sales amounted to SEK 35 million (14) in the quarter, equivalent to growth of 138 percent adjusted for currency effects. Disposables delivered organic growth of 100 percent.

Production of Kidney Assist Transport (KAT) is gradually increasing, although the introduction continues on a selective basis. KAT has now been fully launched in the Netherlands, where it is used for all DCD kidneys with favorable results. To date, we have completed a selective launch in the US, Australia, Sweden and Spain. The initial customer response is positive, confirming the positive clinical results seen in studies such as the one published in The Lancet (2020). There has been considerable interest in the US, and XVIVO took the important step of introducing KAT in the first OPO (Organ Procurement Organization) in October. OPOs provide a majority of kidney perfusion in the US and are an important target group, while also providing a contact point with new transplant centers. XVIVO's top priority is to continue to increase volumes of produced sterile disposables. At a pace with production improving, we are seeing gradually increased product sales.

The **Services** business area, which includes our organ recovery service in the US, had organic growth of 68 percent. We strengthened our organization during the year, focusing on establishing stable, regional hubs that can serve our customers more efficiently. The organizational integration of STAR Teams into XVIVO was completed in the quarter and we are now marketing our services relating to organ retrieval under the XVIVO brand. The work continues to strengthen the customer offering under the joint brand, with a focus on clinical quality as well as efficient logistics and communication.

We continue to deliver healthy gross margins in both Thoracic and Abdominal. The margin in Thoracic was 86 percent (84), and the Abdominal margin was 61 percent (51). We presented a strong EBITDA margin again in the quarter – adjusted for previously announced integration costs, the margin was 19 (10) percent.

The new issue in September raised SEK 440 million for the company before transaction costs and was completed with no discount in an accelerated book-building procedure. The net proceeds are intended for three important purposes, all of which represent a fundamental part of our strategic plan: to bring our heart preservation technology, which now also includes DCD donors, and our liver perfusion technology to the US market after clinical trials in the shortest time possible. We will also finance a strong increase in the production of disposables, with the aim of ensuring delivery capacity and reducing the cost of goods sold. We feel that we have strong support from our shareholders and are determined to deliver according to plan.

"Strong support from our shareholders means that we are now ready to deliver on our strategy"

In the third quarter we saw further indications of the potential of our heart preservation technology. In the US, the protocol has been updated to include DCD donors and on October 14, Duke University Hospital became the first clinic to complete a heart transplant in the US trial. In Australia, use of the technology through special permits continued with favorable clinical results, and to date in the year approximately 30 percent of the country's heart transplants have been carried out using our technology.

In May, we announced in a press release that we had included all of the 202 patients in the European study. This study forms the basis for obtaining regulatory approval in Europe, known as CE-marking, which enables marketing and sales of the heart technology. According to schedule, we submitted the technical documentation for inspection by our Notified Body in the third quarter.

Last, but not least, for the second time in history a successful xenotransplant has been completed where a human received a heart from a pig. This was achieved by a team of researchers at University of Maryland School of Medicine in the US, where XVIVO's technology enabled preservation of the pig heart before transplant.

Given the continued growth in machine perfusion, our strong financial position and the great interest in our US clinical studies, we are looking to next year with confidence.

Christoffer Rosenblad, CEO

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.

Business concept and goals

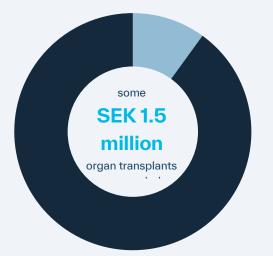
XVIVO's business concept is to develop and market effective, innovative technology for preserving, transporting and assessing organs outside the body while awaiting transplant, and to facilitate the transplant process by offering services in the form of organ recovery and organ perfusion.

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 **150,000**

organ transplants each year, only

10% of total global demand is met XVIVO's offer increases the availability of transplantable organs

Our business areas



Thoracic







Services

Compilation of net sales and EBITDA

SEK Thousands	January- September 2023	January- September 2022	July-September 2023	July-September 2022	January- December 2022
Net Sales Thoracic	285 908	208 188	90 884	71 226	296 353
Net Sales Abdominal	95 866	43 510	35 118	13 683	70 861
Net Sales Services	60 028	32 080	20 612	11 926	48 078
Net Sales Total	441 802	283 778	146 614	96 835	415 292
Gross income Thoracic	238 483	163 113	77 644	57 528	235 676
Gross margin Thoracic, %	83%	78%	85%	81%	80%
Gross income Abdominal	62 112	23 003	21 717	6 516	37 733
Gross margin Abdominal, %	65%	53%	62%	48%	53%
Gross income Services	27 282	15 983	8 237	5 327	23 547
Gross margin Services, %	45%	50%	40%	45%	49%
Gross income Total	327 877	202 099	107 598	69 371	296 956
Gross margin Total, %	74%	71%	73%	72%	72%
Selling expenses	-167 457	-106 680	-66 554	-39 387	-152 398
Administrative expenses	-59 635	-47 913	-13 392	-18 734	-70 979
Research and development expenses	-84 928	-45 384	-27 126	-16 651	-69 343
Other operating revenues and expenses	4 454	1 983	4 776	744	2 173
Operating Income	20 311	4 105	5 302	-4 657	6 409
Amortization and depreciation cost of goods sold	311	543	86	180	744
Depreciation administrative expenses	3 227	2 524	1 134	849	3 402
Amortization of research and development expenses	26 688	22 936	9 060	7 655	31 024
Depreciation selling expenses	9 254	4 888	3 349	1 877	6 997
EBITDA (Operating income before depreciation and amortization)	59 791	34 996	18 931	5 904	48 576
EBITDA, %	14%	12%	13%	6%	12%
EBITDA (adjusted) 1 ⁾	81 416	36 635	27 986	9 908	56 452
EBITDA (adjusted), %	18%	13%	19%	10%	14%

1) Adjusted for effect from costs attributable to business integration. Net adjustment totals SEK -9.1 (-4.0, which related to acquisition costs) million for the quarter. Net adjustment for the period totals SEK -21.6 (-1.6, which consisted of a reversal of a provision for cash-based incentive program for employees outside Sweden of SEK 6.3 million, integration costs of SEK -3.9 million and acquisition costs of SEK -4.0 million) million.

Summary

The quarter July - September 2023

Net sales and income

After two strong quarters at the start of the year, XVIVO followed up with an equally strong third quarter. Net sales in the quarter amounted to SEK 146.6 million (96.8), equivalent to growth of 51 percent year-on-year. The organic growth was 37 percent, acquired growth was 5 percent and the remaining 9 percent constituted currency effects. All business areas demonstrated solid growth. For a description of developments in each business area, see pages 13-14.

The total gross margin for the quarter was 73 percent (72). During the quarter, the gross margin for disposables increased year-on-year for both Thoracic and Abdominal, with a margin of 86 percent (84) for Thoracic and 61 percent (51) for Abdominal. For comments regarding the margins in each business area, see pages 13-14.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 18.9 million (5.9), corresponding to an EBITDA margin of 13 percent (6). EBITDA was affected by integration costs of SEK -9.1 million (-4.0, which related to acquisition costs). Adjusting for these items, EBITDA amounted to SEK 28.0 million (9.9), corresponding to an adjusted EBITDA margin of 19 percent (10).

Operating income (EBIT) amounted to SEK 5.3 million (-4.7). EBIT adjusted for the aforementioned costs amounted to SEK 14.4 million (-0.7).

Selling expenses in relation to total sales amounted to 45 percent (40) for the quarter and included integration costs of SEK -7.7 million (-2.0). R&D expenses amounted to 19 percent (17) of sales. Administrative expenses amounted to 9 percent (19) and included integration costs of SEK -1.6 million (-6.0).

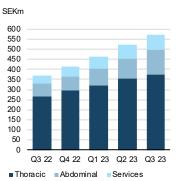
Capitalization and amortization

During the quarter, SEK 21.5 million (27.9) 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 heart and liver transplantation in the US and Europe. Amortization of capitalized development expenditure amounted to SEK 7.3 million (6.5) in the quarter.

Cash flow

Cash flow from operating activities strengthened in the quarter and amounted to SEK 24.8 million (17.0), primarily as a result of strong operating income before depreciation and amortization. Cash flow from investing activities amounted to SEK -28.1 million (-33.7), of which SEK -21.7 million (-28.0) was invested in intangible assets and SEK -6.5 million (-6.1) was invested in tangible assets. Cash flow from financing activities amounted to a net SEK -427.6 million (-1.6), primarily due to proceeds from the new issue of SEK 429.9 million net of transaction costs. Exchange rate differences impacted the cash flow for the quarter by SEK -1.6 million (15.0). Cash and cash equivalents at the end of the quarter amounted to SEK 594.3 million (314.6).

Net sales by business area (R12)



EBITDA and EBITDA margin (adjusted, R12)



Significant events during the quarter

Directed new share issue raised SEK 440 million.

XVIVO carried out a directed share issue of 1,600,000 shares at a subscription price of SEK 275 per share, raising gross proceeds of SEK 440 million before transaction costs of approximately SEK 10 million for the company. The subscription price was determined in an accelerated book-building procedure. Investors in the directed issue include existing and new shareholders such as Bure Equity AB, the Fourth AP Fund, Swedbank Robur Fonder, Eccenovo, Handelsbanken Fonder AB through the investment fund Hälsovård Tema, the Third AP Fund and a tier-one global international investor.

The net proceeds from the Directed Issue are intended to be used for:

1) Increased investments in US clinical trial infrastructure and support to create an efficient FDA PMA regulatory approval process for the heart preservation technology;

2) Fast-track the preparation and start of the clinical trial and FDA PMA regulatory approval process for Liver Assist; and

3) Scale-up of disposable production to ensure delivery capacity and decrease in cost of goods sold.

Through the Directed Issue, the number of shares and votes in XVIVO Perfusion AB (Publ) increased by 1,600,000, as announced on September 29, 2023. As of September 30, the total number of shares and votes was 31,499,470.

US FDA grants XVIVO approval to include DCD hearts in IDE Clinical Trial

The US Food & Drug Administration (FDA) has approved XVIVO's Investigational Device Exemption (IDE) supplement for its heart preservation clinical trial to now include Donation after Circulatory Death (DCD) hearts. This permits clinical trial sites to utilize XVIVO's heart technology to preserve hearts from DCD donors. 141 patients will be enrolled at up to 20 US hospitals. The number of patients is unchanged, but this change will allow five additional clinics to participate in the trial.

XVIVO's heart preservation technology was used in a second successful xenotransplant (heart from pig to human)

On September 20, 2023, the world's second successful heart xenotransplant from pig to human was completed. Like for the first transplantation, a team of researchers at University of Maryland School of Medicine in the US were behind the achievement. After removing the heart from the pig, XVIVO's preservation technology and patented solution was used to preserve the heart in optimal condition before transplant. The patient was a 58-year-old critically ill man with terminal heart failure who did not qualify for conventional treatment methods.

One of the biggest challenges in transplantation is the shortage of organs. Xenotransplantation, i.e. transplantation between species, presents a potential solution to the critical organ shortage. Groundbreaking research using XVIVO's heart preservation technology has achieved long-term survival after xenotransplants of hearts from genetically modified pigs to primates in recent years.

XVIVO initiates strategic collaboration with MTJ Aviation to strengthen organ retrieval services in the US

XVIVO has signed a strategic collaboration agreement with MTJ Aviation, a US company specializing in healthcare transport. The agreement is a positive consequence of the decision to integrate STAR Teams with the XVIVO brand. Reliable organ transports have become increasingly important for transplantation clinics in the US following recent changes to US organ allocation policy. Escalating logistics complexity and ensuing increased costs to clinics have led to the emergence of a more customized and efficient transportation process. Alongside MTJ Aviation, XVIVO will address this need by establishing shared flight hubs on the US East Coast and in the Mid West. Each hub will have a dedicated surgical team and a light jet plane dedicated to XVIVO's operations.

XVIVO has decided to conclude further patient inclusion in the PrimECC® study

PrimECC is a solution used to prepare heart-lung machines ahead of heart surgery. The product is both CE marked and patent protected and has been developed with the aim of reducing complications after surgery. A clinical trial in PrimECC was initiated in 2020, with the aim of expanding and strengthening existing clinical data. Unfortunately, the rate of patient inclusion did not live up to expectations, and the study is not expected to be completed within a reasonable time frame. XVIVO has therefore decided to halt further patient inclusion in the study. The study data will be analyzed and the strategic potential evaluated.

So far, SEK 14 million has been invested in the clinical trial in PrimECC. If XVIVO eventually decides to terminate the product, this would result in impairment of intangible assets totaling SEK 14 million. XVIVO expects to make a decision regarding the future of PrimECC within a three-six month period.

The period January - September 2023

Net sales and income

Sales in the period amounted to SEK 441.8 million (283.8), equivalent to growth of 56 percent year-on-year. Organic growth was 39 percent, acquired growth 6 percent, and the remaining 11 percent constituted currency effects. All business areas demonstrated solid growth. For a description of development within each business area, see pages 13-14.

The total gross margin for the period was 74 percent (71). During the period, the gross margin for disposables increased year-on-year both for Thoracic and Abdominal, with a margin of 85 percent (84) for Thoracic and 65 percent (53) for Abdominal. For comments regarding the margins in each business area, see pages 13-14.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 59.8 million (35.0), corresponding to an EBITDA margin of 14 percent (12). EBITDA was affected by integration costs of SEK -21.6 million (-1.6, which consisted of a reversal of a provision for cash-based incentive program for employees outside Sweden of SEK 6.3 million, integration costs of SEK -3.9 million and acquisition costs of SEK -4.0 million). Adjusting for these items, EBITDA amounted to SEK 81.4 million (36.6), corresponding to an adjusted EBITDA margin of 18 percent (13).

Operating income (EBIT) amounted to SEK 20.3 million (4.1). EBIT adjusted for the aforementioned costs amounted to SEK 41.9 million (5.7).

Selling expenses as a proportion of sales amounted to 38 percent (37) for the period. R&D expenses amounted to 19 percent (16) of sales. The increase was primarily due to changes in internal resource allocation and investments in the organization. Administrative expenses amounted to 13 percent (17) of sales.

Capitalization and amortization

During the period, SEK 66.9 million (85.4) 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 heart and liver transplantation in the US and Europe. Amortization of capitalized development expenditure amounted to SEK 21.8 million (19.6) in the period.

Cash flow

Cash flow from operating activities strengthened in the period, amounting to SEK 28.2 million (6.1). Cash flow from investing activities amounted to SEK -109.0 million (-120.6), impacted by contingent consideration related to the acquisition of Avionord (XVIVO S.r.l.) of SEK -10.9 million, the final part payment of the initial purchase consideration regarding the acquisition of STAR Teams of SEK -6.8 million, investments in intangible assets of SEK -67.6 million (-86.4) and investments in property, plant and equipment of SEK -23.7 million (-14.1). Cash flow from financing activities amounted to a net of SEK 422.3 million (-4.0) primarily attributable to proceeds from the new issue of SEK 429.9 million net of transaction costs. Cash and cash equivalents at the end of the period amounted to SEK 594.3 million (314.6).

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 86 percent (84) at the end of the period. The company's total credit facility consists of an overdraft facility, which amounted to SEK 30 million (30) at the end of the period, of which SEK 0.0 million (0.0) was utilized.

Net sales

SEK 442 million

Gross margin

74_%

Adjusted EBITDA

18%

Successful integration of Avionord M&P

The integration of our Italian distributor was completed as planned in the first quarter. Avionord M&P was acquired at the end of 2022 and the business now operates under the name XVIVO S.r.l. The company markets XVIVO's technologies in combination with a perfusion service and is the leading operator on the Italian market for organ perfusion.

Significant interest in XVIVO's heart technology in Australia and New Zealand

The last patient in the investigator-initiated heart preservation study in Australia and New Zealand received a transplant towards the end of 2022. Pending regulatory approval for these geographies, which is dependent on CE marking under MDR, special permits have been granted that allow hearts to be treated with products that have not received regulatory approval. There is very strong interest in continuing to use XVIVO's technology. Four out of five trial centers purchased and used our products in the period, and the fifth center is expected to follow shortly. Approximately 30 percent of these countries' heart transplants were performed using our technology in the period.

Benefits of XVIVO's heart preservation technology after DCD donation have also been demonstrated

The Journal of Heart and Lung Transplantation published an article in the first quarter¹ from a research team led by professor H Eiskjaer, Aarhus, Denmark. In a large animal model, the team successfully showed the potential for using XVIVO's heart preservation technology for hearts from DCD² donors. The study shows that DCD hearts can successfully be transplanted both after direct procurement and after normothermic regional perfusion (NRP) of the donor organ if XVIVO's technology is used.

Strengthened proof of the benefits of cold oxygenated perfusion of liver after DBD donation

XVIVO's liver perfusion technology, Liver Assist, offers hypothermic oxygenated perfusion (HOPE) for the liver. The advantages of the technology over traditional static cold storage for DCD livers were highlighted in The New England Journal of Medicine in 2021. During the first quarter, The Journal of Hepathology³ published the results of a randomized multicenter trial showing positive effects if HOPE is also used for livers from DBD⁴ donors. Today the majority of transplanted livers in the world are DBD donations.

XVIVO's IDE application for its heart preservation technology gained FDA approval in the US

The US Food & Drug Administration (FDA) has approved XVIVO's Investigational Device Exemption (IDE) application for its heart preservation technology. The approval allows XVIVO to start the "PRESERVE Clinical Trial: A Prospective, Multi-center, Single-Arm, Open-Label Study of Hearts Transplanted after Non-Ischemic Heart PRESERVation from Extended Donors".

The PRESERVE multicenter clinical trial will evaluate safety and effectiveness to be used in support of Pre-Market Approval (PMA). The trial will enroll 141 patients across 20 leading transplant centers in the US. Amongst other inclusion criteria, the trial will allow transplant centers to include donor hearts from older donors (defined as aged 50+), DCD-donors and hearts from long-distance donors. By including long-distance donors, XVIVO's goal is to further validate the findings from the investigator-initiated NIHP study in Australia and New Zealand which was presented at ISHLT in April 2023 – that non-ischemic preservation of donor hearts using XVIVO's innovative technology can enable uncompromised organ preservation quality, despite significantly extended transport times.

Patient inclusion completed in European clinical trial with XVIVO's heart preservation technology

XVIVO's innovative heart technology is currently being investigated in a randomized controlled clinical trial across 15 leading transplant centers in 8 European countries. 202 patients have gone through a transplantation in the trial which means inclusion of all planned participants has now been completed. The next step is a one-year follow-up phase where patient outcomes will be collected and monitored before the trial is closed and data presented.

XVIVO strengthens it service offering in the US through the commercial integration of STAR Teams

XVIVO acquired STAR Teams, an organ recovery service in the US, in November 2021. To meet rapidly growing demand for recovery services in the US and in order to strengthen the organization's operations and commercial offering, XVIVO has during the period integrated STAR Teams into the XVIVO brand. Non-recurring costs associated with the integration amounted to a total of approximately SEK 22 million. The integration strongly supports XVIVO's strategic objective of becoming the "preferred partner in the transplant process".

Change in number of shares and votes in XVIVO Perfusion AB (publ)

The number of shares and votes in XVIVO Perfusion AB (publ) increased by 67,551 in the second quarter as a result of the new share issue in relation to the contingent consideration received for the acquisition of XVIVO S.r.l The contingent consideration totaling SEK 27.2 million was paid in 40 percent cash and the remaining 60 percent in the form of shares in XVIVO. The right to subscribe for the shares was transferred to Avionord S.r.l. - the seller of the shares in XVIVO S.r.l.

The number of shares and votes in XVIVO Perfusion AB (publ) increased further during the third quarter as a result of the directed share issue of 1,600,000 shares that the company announced on 29 September 2023. As of September 30, the number of shares and votes amounts to 31,499,470.

¹https://www.jhltonline.org/article/S1053-2498(23)00033-5/fulltext

² DCD: Donation after circulatory death Donation after circulatory death

³ https://www.journal-of-hepatology.eu/article/S0168-8278(23)00012-0/fulltext#%20 ⁴ DBD: Donation after brain death Donation after brain death

Significant events after the end of the period

The first transplant was completed in the US heart preservation clinical trial

On October 14, 2023, Duke University Hospital in Durham, N.C, performed the first heart transplant in the US using XVIVO's Non-Ischemic Heart Preservation (NIHP) device and solution as part of the PRESERVE clinical trial.

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 FDA clearance for warm perfusion of marginal lungs. In heart transplantation, XVIVO's products are in a clinical study phase. In 2023, XVIVO initiated sales activities in clinical heart transplantation in Australia and New Zealand, while pre-clinical sales have been underway for a number of years aimed at supporting research studies, including xenotransplantation.

Summary

	January- September		July-September	July-September	Full year
SEK Thousands	2023	2022	2023	2022	2022
Net sales	285 908	208 188	90 884	71 226	296 353
Disposables	274 888	191 836	89 833	69 188	276 589
Machines	11 020	16 352	1 051	2 038	19 764
Gross margin, %	83	78	85	81	80
Disposables	85	84	86	84	84
Machines	37	17	22	-40	15

The quarter July - September 2023

Thoracic delivered a quarter of continued positive growth in year-on-year terms. Sales amounted to SEK 90.9 million (71.2), equivalent to growth of 28 percent year-on-year or 20 percent adjusted for currency effects. Sales of disposables delivered growth of 30 percent.

Machine perfusion accounted for 46 percent (51) of net sales. Static preservation and other sales accounted for the remainder of net sales.

The gross margin for disposables increased to 86 percent (84), primarily driven by strong sales in static preservation (Perfadex Plus) products.

The period January - September 2023

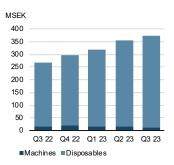
Sales increased by 37 percent in the period compared to the corresponding period in the previous year and amounted to SEK 285.9 million (208.2). The increase is equivalent to an increase of 28 percent adjusted for currency effects.

Sales of disposables increased by 43 percent and amounted to SEK 274.9 million (191.8). Organic growth amounted to 34 percent in local currencies.

Machine perfusion accounted for 50 percent (49) of net sales. Static preservation and other sales accounted for the remainder of net sales.

Gross margin for disposables increased to 85 percent (84).

Net sales Thoracic (R12)



Net sales per product category Thoracic (Q3)



Machine perfusion, 46%
Static preservation, 52%
Other, 2%

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. In 2023 and 2024 we will accelerate the introduction of the company's kidney preservation product, Kidney Assist Transport, on our main markets in the US and Europe.

Summary

	January- September		July-September	July-September	Full year
SEK Thousands	2023	2022	2023	2022	2022
Net sales	95 866	43 510	35 118	13 683	70 861
Disposables	85 490	37 954	30 821	12 640	59 877
Machines	10 376	5 556	4 297	1 043	10 984
Gross margin, %	65	53	62	48	53
Disposables	65	53	61	51	54
Machines	67	49	70	9	51

The quarter July - September 2023

Sales amounted to SEK 35.1 million (13.7) in the quarter, representing an increase of 157 percent year-on-year. Adjusted for currency effects, growth totaled 138 percent. The increase for disposables was strong at 144 percent, or 129 percent adjusted for currency effects, of which organic growth accounted for 100 percent and acquired growth for 29 percent. The revenue was primarily generated in Europe and approximately 70 percent related to liver perfusion.

The gross margin for disposables increased to 61 percent (51), driven by price increases and an integrated product and service offering on the company's largest abdominal market, Italy.

The period January - September 2023

Sales in the period amounted to SEK 95.9 million (43.5), equivalent to growth of 120 percent year-on-year. Growth was 102 percent adjusted for exchange rate effects. The increase for disposables was strong at 125 percent, or 108 percent adjusted for currency effects, of which organic growth accounted for 71 percent and acquired growth for 36 percent.

The gross margin for disposables increased to 65 percent (53), driven by price increases and an integrated product and service offering on the company's largest abdominal market, Italy.

Services

The Services business area comprises STAR Teams' organ recovery operations in the US in the area of thoracic. Organ recovery means 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. STAR Teams currently offers services to transplantation clinics in the Midwest and on the East Coast.

Summary

	January- September	January- September	July-September	July-September	Full year
SEK Thousands	2023	2022	2023	2022	2022
Net sales	60 028	32 080	20 612	11 926	48 078
Gross margin, %	45	50	40	45	49

The quarter July - September 2023

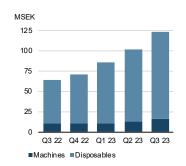
STAR Teams' sales experienced organic growth of 68 percent year-on-year, primarily driven by an increased customer base. The number of organ retrievals increased by 17 percent year-on-year. The gross margin was 40 percent (45), primarily due to investments in the organization. The margin is expected to increase as the customer base expands and economies of scale are generated.

The period January - September 2023

STAR Teams' sales experienced organic growth of 75 percent in year-on-year terms, primarily driven by an increased customer base. The number of organ recoveries increased by 25 percent. Demand for organ recovery services from US clinics continues to grow, and operations were reorganized in the period in order to better meet the demand. The gross margin was 45 percent (50) and is expected to increase as the customer base expands and economies of scale are generated.

XVIVO

Net sales Abdominal (R12)



Net sales by product category, Abdominal (Q3)



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

Organ recoveries in Q3



R&D portfolio

Development projects

Project	Description	Status
Heart transplantation	The primary restriction on the number of heart transplants possible today comes from the number of available, usable donated organs based on current technology, coupled with the time a donated heart can survive outside the body. In collaboration with Professor Stig Steen, XVIVO has developed a comprehensive solution comprising fluids and machinery that prevents damage to the heart and preserves its function during transport. The technology contributes to improved results after heart transplantation and enables longer transports. In the ongoing clinical trials, the results from the transplant of donated hearts transported and preserved using XVIVO's method are evaluated and compared to the results after conventional ice-box method.	XVIVO has a program of clinical multicenter studies. These will form the basis for the application for regulatory approval for the products in all major markets worldwide. During the year, several important milestones were reached in clinical trials using XVIVO's heart technology. Complete data from the Australian study was presented at ISHLT's annual meeting. Patients receiving heart transplants using XVIVO's technology had a 100 percent survival rate after 30 days, and only one patient was treated using mechanical circulation support. This was despite extreme transport periods for the hearts of up to 9 hours. In the second quarter, the final patient was included in XVIVO's European multicenter study with 15 participants. The study is now in the follow-up and compilation phase. The data gathered is used in the application process for regulatory approval and will be presented in its entirety in 2024. In the second quarter, the FDA approved XVIVO's IDE application for the planned clinical trial with up to 20 clinics and allowed the inclusion of DCD hearts in the study. The first participating centers were trained in October, and the first patient in the trial has now been transplanted.
Kidney transplantation	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.	An international study published in <i>The Lancet</i> in 2020 illustrates the advantages for the recipient when the kidney is transported perfused with an oxygenated solution. This is the technology that is unique to XVIVO and is currently being launched in the US. This step has taken kidney technology into a more mature phase. 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 have started or are in the start-up phase.
Liver transplantation	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 reduces the risk of serious complications in many cases. Over the past year, using warm perfusion to evaluate liver function outside the body ahead of transplant has attracted significant interest.	The results of a study after using XVIVO's technology were published in <i>The New England Journal of Medicine</i> in 2021 and demonstrate significant benefits of cold oxygenated machine perfusion of livers prior to transplantation with donation after circulatory death (DCD). In the year, a large number of clinical studies were published that demonstrate significant advantages associated with XVIVO's technology. As XVIVO's Liver Assist allows for both warm and cold perfusion through one or two vessels, the technology is used in several ongoing studies in different clinical scenarios. In order to gain approval for the liver technology in the US, XVIVO is preparing clinical trials in the US and has initiated discussions with the FDA.

Research projects

Project	Description	Status
Xenotransplantation	Xenotransplantation involves the use of non-human organs in transplantation. The method is currently at the research stage for several organs.	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 was used to preserve the heart before transplantation. The initial communication has been positive and has again attracted significant media interest. 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.

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 2022. The Annual Report and our key policies are available at www.xvivogroup.com.

Organization and employees

The XVIVO Group has 144 employees, of whom 68 are women and 76 men. Of these, 49 are employed in Sweden and 95 outside Sweden. The head office is located in Gothenburg, Sweden and our subsidiaries are located in Lund, Sweden, the US, Italy, France, Brazil, China, Australia and the Netherlands. 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 2022, available at <u>www.xvivogroup.com</u>.

Nomination Committee for the 2023 AGM

The following have been appointed to be part of XVIVO Perfusion AB's (publ) Nomination Committee for the 2023 Annual General Meeting:

Henrik Blomquist, appointed by Bure Equity AB Thomas Ehlin, appointed by Fourth AP Fund Fredrik Stenkil, appointed by Swedbank Robur Fonder AB 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 32.4 percent of all shares in the company on August 31, 2023.

Annual General Meeting and Annual Report

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on April 25, 2024 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-43153 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 2023 is expected to be available to download from the XVIVO website in the week beginning April 1, 2024.

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, in terms of both scope and significance, in line with transplantation clinics sharpening their focus on increasing the number of transplants. This trend is reflected in the progress made in 2023 with positive sales growth across all business areas to date. Due to growing interest in our product and service offering across all organ areas, we anticipate continued long-term sustainable growth.

The priorities ahead of 2024 are clear and follow our strategic plan: continued investment in machine perfusion and service models for existing products on the market, successfully carrying out our clinical multicenter studies in the US (heart and liver), and investment in new production facilities to secure future delivery capacity of disposables at a level ten times higher than today.

Although XVIVO and the transplantation industry in general are showing significant growth, there is uncertainty in the wider world. The geopolitical situation unfortunately remains tense. XVIVO currently has very limited sales exposure to Eastern Europe and the procurement chain is not exposed to these markets. Our manufacturing takes place either in Western Europe or the US. Accordingly, we currently do not assess that the conflict in Ukraine and the Israel and Gaza conflict are having any direct negative impact on XVIVO's operations.

We estimate that the number of transplantations globally will continue to grow, which is driven by increased machine perfusion and service models that facilitate the operations of transplantation clinics. XVIVO will continue to invest in the significant market potential that exists.

Significant events after the end of the period

No significant 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.

Gothenburg, October 24, 2023

Christoffer Rosenblad CEO

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 Tuesday, October 24, 2023 at 7.30 am CEST.



Financial calendar

- Year-End Report 2023: Thursday, January 25, 2024
- Interim Report January-March 2024: Wednesday, April 24, 2024
- Interim Report January-June 2024: Friday, July 12, 2024
- Interim Report January-September 2024: Thursday, October 24, 2024



Conference call

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

For access via conference call, click here

For access via webcast, click here



Contact

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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 2023 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. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with ISA and generally accepted auditing standards Other. 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, 2023

KPMG AB

Daniel Haglund Authorized public Accountant, Auditor in charge

Financial statements

Condensed Consolidated Statement of Net Income

	January- September	January-	lulu Cantamban	July-September	January-
SEK Thousands	September 2023	September 2022	July-September 2023		December 2022
Net sales	441 802	283 778	146 614		415 292
Cost of goods sold	-113 925	-81 679	-39 016	-27 464	-118 336
Gross income	327 877	202 099	107 598	69 371	296 956
Selling expenses	-167 457	-106 680	-66 554	-39 387	-152 398
Administrative expenses	-59 635	-47 913	-13 392	-18 734	-70 979
Research and development expenses	-84 928	-45 384	-27 126	-16 651	-69 343
Other operating revenues and expenses	4 454	1 983	4 776	744	2 173
Operating income	20 311	4 105	5 302	-4 657	6 409
Financial income and expenses	8 648	15 458	-4 348	7 649	15 905
Income after financial items	28 959	19 563	954	2 992	22 314
Taxes	-5 613	-1 870	1 330	2 406	-3 887
Net income	23 346	17 693	2 284	5 398	18 427
Attributable to					
Parent Company's shareholders	23 346	17 693	2 284	5 398	18 427
Earnings per share, SEK	0.78	0.60	0.08	0.18	0.62
Earnings per share, SEK ¹⁾	0.78	0.60	0.08	0.18	0.62
Average number of outstanding shares	29 935 147	29 505 699	30 139 116	29 512 733	29 525 946
Average number of outstanding shares 1)	29 935 147	29 505 699	30 139 116	29 512 733	29 525 946
Number of shares at closing day	31 499 470	29 561 967	31 499 470	29 561 967	29 831 919
Number of shares at closing day ¹⁾	31 499 470	29 561 967	31 499 470	29 561 967	29 831 919
EBITDA (Operating income before depreciation and amortization)	59 791	34 996	18 931	5 904	48 576
Depreciation and amortization on intangible assets	-23 073	-20 726	-7 725	-6 891	-27 871
Depreciation and amortization on tangible assets	-16 407	-10 165	-5 904	-3 670	-14 296
Operating income	20 311	4 105	5 302	-4 657	6 409

¹⁾ After dilution

Consolidated Statement of Total Comprehensive Income

	January- September		July-September	July-September	January- December
SEK Thousands	2023	2022	2023	2022	2022
Net income	23 346	17 693	2 284	5 398	18 427
Other comprehensive income					
Items that may be reclassified to the income statement					
Exchange rate differences	25 051	77 866	-10 520	30 381	65 693
Total other comprehensive income	25 051	77 866	-10 520	30 381	65 693
Total comprehensive income	48 397	95 559	-8 236	35 779	84 120
Attributable to					
Parent Company's shareholders	48 397	95 559	-8 236	35 779	84 120

Condensed Consolidated Statement of Financial Position

SEK Thousands	230930	220930	221231
ASSETS			
Goodwill	645 409	525 648	625 319
Capitalized development expenditure	593 627	523 498	544 510
Other intangible fixed assets	8 029	8 547	8 484
Fixed assets	78 193	36 978	47 579
Financial assets	38 231	40 853	39 684
Total non-current assets	1 363 489	1 135 524	1 265 576
Inventories	145 618	89 996	106 566
Current receivables	133 740	101 418	114 397
Liquid funds	594 261	314 561	246 545
Total current assets	873 619	505 975	467 508
Total assets	2 237 108	1 641 499	1 733 084
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity, attributable to the Parent Company's shareholders	1 928 115	1 381 633	1 430 136
Long-term interest-bearing liabilities	16 070	1 387	4 455
Long-term non-interest-bearing liabilities	150 857	172 110	163 597
Short-term interest-bearing liabilities	9 455	4 158	5 550
Short-term non-interest-bearing liabilities	132 611	82 211	129 346
Total shareholders' equity and liabilities	2 237 108	1 641 499	1 733 084

Condensed Consolidated Cash Flow Statement

	January- September	January-	July-September	luly Sontombor	January- December
	2023	2022	2023	2022	2022
Income after financial items	28 959	19 563	954	2 992	22 314
Adjustment for items not affecting cash flow	31 953	13 301	19 782	2 785	27 510
Paid taxes	-3 365	-1 592	-1 830	-556	199
Change in inventories	-34 141	4 209	-22 702	-6 304	-6 325
Change in trade receivables	-13 047	-19 213	-338	11 052	-26 860
Change in trade payables	17 801	-10 201	28 974	7 002	11 018
Cash flow from operating activities	28 160	6 067	24 840	16 971	27 856
Cash flow from investing activities	-109 034	-120 570	-28 087	-33 723	-197 624
Cash flow from financing activities	422 273	-4 042	427 626	-1 621	-6 842
Cash flow for the period	341 399	-118 545	424 379	-18 373	-176 610
Liquid funds at beginning of period	246 545	398 696	171 437	317 885	398 696
Exchange rate difference in liquid funds	6 317	34 410	-1 555	15 049	24 459
Liquid funds at end of period	594 261	314 561	594 261	314 561	246 545

Consolidated Changes in Shareholders' Equity

	Attributable to Parent Company's shareholders				
				Retained earnings incl.	Sum
		Other paid in	_	profit for the	shareholders
SEK Thousands	Share capital	capital	Reserves	year	equity
Shareholders' equity as of January 1, 2022	754	1 253 330	22 088	9 278	1 285 450
Total comprehensive income January - September 2022	-	-	77 866	17 693	95 559
Issuing of new shares efter deduction of incremental costs directly related to issuing new shares net of tax	2	-240	-	47	-191
Share warrant program	-	815	-	-	815
Shareholders' equity as of September 30, 2022	756	1 253 905	99 954	27 018	1 381 633
Total comprehensive income October - December 2022	-	-	-12 173	734	-11 439
Issuing of new shares efter deduction of incremental costs directly related to issuing new shares net of tax	6	59 934	-	2	59 942
Shareholders' equity as of December 31, 2022	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 efter 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

Condensed Consolidated Statement of Net Income by quarter

	Jul-Sep	Apr-Jun	Jan-Mar	Oct-Dec	Jul-Sep	Apr-Jun	Jan-Mar	Oct-Dec
SEK Thousands	2023	2023	2022	2022	2022	2022	2021	2021
Net sales	146 614	154 573	140 615	131 514	96 835	94 289	92 654	85 863
Cost of goods sold	-39 016	-39 111	-35 798	-36 657	-27 464	-26 783	-27 432	-22 873
Gross income	107 598	115 462	104 817	94 857	69 371	67 506	65 222	62 990
Selling expenses	-66 554	-52 528	-48 375	-45 718	-39 387	-37 774	-29 519	-34 974
Administrative expenses	-13 392	-27 258	-18 985	-23 066	-18 734	-14 779	-14 400	-21 095
Research and development costs	-27 126	-31 629	-26 173	-23 959	-16 651	-12 075	-16 658	-15 476
Other operating revenues and expenses	4 776	-245	-77	190	744	1 260	-21	255
Operating income	5 302	3 802	11 207	2 304	-4 657	4 138	4 624	-8 300
Financial income and expenses	-4 348	7 638	5 358	447	7 649	6 244	1 565	18 537
Income after financial items	954	11 440	16 565	2 751	2 992	10 382	6 189	10 237
Taxes	1 330	-4 554	-2 389	-2 017	2 406	-2 852	-1 424	1 952
Net income	2 284	6 886	14 176	734	5 398	7 530	4 765	12 189
Attributable to								
Parent Company's shareholders	2 284	6 886	14 176	734	5 398	7 530	4 765	12 189
Earnings per share, SEK	0.08	0.23	0.48	0.02	0.18	0.26	0.16	0.42
Earnings per share, SEK ¹⁾	0.08	0.23	0.48	0.02	0.18	0.26	0.16	0.41
Average number of outstanding shares	30 139 116	29 872 450	29 831 919	29 602 717	29 512 733	29 512 733	29 498 666	29 241 732
Average number of outstanding shares ¹⁾	30 139 116	29 872 450	29 831 919	29 602 717	29 512 733	29 512 733	29 872 666	29 615 732
Number of shares at closing day	31 499 470	29 899 470	29 831 919	29 831 919	29 561 967	29 561 967	29 498 666	29 498 666
Number of shares at closing day ¹⁾	31 499 470	29 899 470	29 831 919	29 831 919	29 561 967	29 561 967	29 872 666	29 872 666
EBITDA (Operating income before depreciation and amortization)	18 931	17 216	23 644	13 580	5 904	14 399	14 693	-96
Depreciation and amortization on intangible assets	-7 725	-7 715	-7 633	-7 145	-6 891	-6 929	-6 906	-5 336
Depreciation and amortization on tangible assets	-5 904	-5 699	-4 804	-4 131	-3 670	-3 332	-3 163	-2 868
Operating income	5 302	3 802	11 207	2 304	-4 657	4 138	4 624	-8 300
¹⁾ After dilution								

1) After dilution

Consolidated Statement of Total Comprehensive Income by quarter

SEW Thomsondo	Jul-Sep	Apr-Jun	Jan-Mar	Oct-Dec	Jul-Sep	Apr-Jun	Jan-Mar	Oct-Dec
SEK Thousands Net income	2023 2 284	2023 6 886	2022 14 176	2022 734	2022 5 398	2022 7 530	2021 4 765	2021 12 189
Other comprehensive income								
Items that may be reclassified to the income statement:								
Exchange rate differences	-10 520	32 690	2 881	-12 173	30 381	37 862	9 623	15 394
Total other comprehensive income	-10 520	32 690	2 881	-12 173	30 381	37 862	9 623	15 394
Total comprehensive income	-8 236	39 576	17 057	-11 439	35 779	45 392	14 388	27 583
Attributable to								
Parent Company's shareholders	-8 236	39 576	17 057	-11 439	35 779	45 392	14 388	27 583

Consolidated Key Ratios

	January- September	January- September	July-September	July-September	January- December
SEK Thousands	2023	2022	2023	2022	2022
Gross margin, %	74	71	73	72	72
Gross margin disposables, %	80	79	80	79	79
EBIT, %	5	1	4	-5	2
EBIT (adjusted), %	9	2	10	-1	3
EBITDA, %	14	12	13	6	12
EBITDA (adjusted), %	18	13	19	10	14
Net margin, %	5	6	2	6	4
Equity/assets ratio, %	86	84	86	84	83
Earnings per share, SEK	0.78	0.60	0.08	0.18	0.62
Shareholders' equity per share, SEK	61.21	46.74	61.21	46.74	47.94
Share price on closing day, SEK	275	134	275	134	183
Market cap on closing day, MSEK	8 647	3 961	8 647	3 961	5 459

Condensed Income Statement for the Parent Company

	January- September	January- September	July-September	July-September	January- December
SEK Thousands	2023	2022	2023		2022
Net sales	198 098	172 870	60 233	58 009	243 737
Cost of goods sold	-48 902	-37 202	-17 637	-13 736	-54 599
Gross income	149 196	135 668	42 596	44 273	189 138
Selling expenses	-51 569	-45 410	-19 467	-15 248	-59 489
Administrative expenses	-50 681	-39 806	-13 432	-11 907	-55 691
Research and development expenses	-51 979	-37 334	-18 691	-12 531	-52 355
Other operating revenues and expenses	49	1 900	-226	574	2 324
Operating income	-4 984	15 018	-9 220	5 161	23 927
Financial income and expenses	12 885	17 963	-2 644	8 651	19 982
Income after financial items	7 901	32 981	-11 864	13 812	43 909
Taxes	-1 963	-7 004	2 441	-2 849	-9 177
Net income	5 938	25 977	-9 423	10 963	34 732

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 14,727 (14,404) thousand, of which SEK 4,982 (4,815) thousand in the quarter.

Condensed Balance Sheet for the Parent Company

SEK Thousands	230930	220930	221231
ASSETS			
Intangible fixed assets	412 288	346 418	363 398
Property, plant and equipment	13 126	10 677	10 775
Financial assets	980 922	792 380	926 531
Total non-current assets	1 406 336	1 149 475	1 300 704
Inventories	43 979	17 696	27 548
Current receivables	50 815	34 739	36 890
Cash and bank	491 229	274 130	196 281
Total current assets	586 023	326 565	260 719
Total assets	1 992 359	1 476 040	1 561 423
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	1 797 286	1 272 871	1 341 567
Provisions	2 023	1 328	1 374
Long-term non-interest-bearing liabilities	138 087	146 138	137 130
Short-term non-interest-bearing liabilities	54 963	55 703	81 352
Total shareholders' equity and liabilities	1 992 359	1 476 040	1 561 423

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 Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities. Accounting principles applied to the Group and the Parent Company correspond, unless otherwise stated below, 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 728 million (416) and SEK 142 million (72) 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 138.1 million (160.2) 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 1.7 million (30.5) in the period and was recognized in financial items. The calculation has been made in accordance with the accounting principles indicated in Note 1.

Financial liabilities measured at fair value

TSEK	230930	220930	221231
Opening balance	170 416	150 676	150 676
Additional purchase considerations	-	-	26 224
Discount of additional purchase considerations	-4 157	-	-
Payment of additional purchase considerations	-34 000	-20 976	-27 999
Exchange-rate differences	5 828	30 459	21 515
Closing balance	138 087	160 159	170 416

Note 3. Net sales

Distribution of net sales

		January-September									
	Thor	acic	Abdo	minal	Serv	ices	Total cons	solidated			
SEK Thousands	2023	2022	2023	2022	2023	2022	2023	2022			
Disposables	274 888	191 836	85 490	37 954	-	-	360 378	229 790			
Machines	11 020	16 352	10 376	5 556	-	-	21 396	21 908			
Service	-	-	-	-	60 028	32 080	60 028	32 080			
Net sales	285 908	208 188	95 866	43 510	60 028	32 080	441 802	283 778			

SEK Thousands		July-September									
	Thorac	cic	Abdor	Abdominal		Services		Total consolidated			
	2023	2022	2023	2022	2023	2022	2023	2022			
Disposables	89 833	69 188	30 821	12 640	-	-	120 654	81 828			
Machines	1 051	2 038	4 297	1 043	-	-	5 348	3 081			
Service	-	-	-	-	20 612	11 926	20 612	11 926			
Net sales	90 884	71 226	35 118	13 683	20 612	11 926	146 614	96 835			

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.

	January-September									
	Thorac	cic	Abdor	ninal	Serv	ices	Total cons	olidated		
SEK Thousands	2023	2022	2023	2022	2023	2022	2023	2022		
Net sales	285 908	208 188	95 866	43 510	60 028	32 080	441 802	283 778		
Cost of goods sold	-47 425	-45 075	-33 754	-20 507	-32 746	-16 097	-113 925	-81 679		
Gross income	238 483	163 113	62 112	23 003	27 282	15 983	327 877	202 099		
Gross margin (%)	83	78	65	53	45	50	74	71		

	July-September									
	Thoracio	•	Abdom	Abdominal		Services		Total consolidated		
SEK Thousands	2023	2022	2023	2022	2023	2022	2023	2022		
Net sales	90 884	71 226	35 118	13 683	20 612	11 926	146 614	96 835		
Cost of goods sold	-13 240	-13 698	-13 401	-7 167	-12 375	-6 599	-39 016	-27 464		
Gross income	77 644	57 528	21 717	6 516	8 237	5 327	107 598	69 371		
Gross margin (%)	85	81	62	48	40	45	73	72		

Geographical areas

	January-September									
	Thoraci	c	Abdom	Abdominal		Services		Total consolidated		
SEK Thousands	2023	2022	2023	2022	2023	2022	2023	2022		
North America	177 112	132 404	6 237	6 439	60 028	32 080	243 377	170 923		
South and Latin America	4 391	4 271	-	-	-	-	4 391	4 271		
EMEA	72 630	61 125	87 629	34 695	-	-	160 259	95 820		
Asia and Pacific	31 775	10 389	2 000	2 375	-	-	33 775	12 764		
Net sales	285 908	208 188	95 866	43 510	60 028	32 080	441 802	283 778		

		July-September									
	Thoracio	;	Abdomin	Abdominal			Total consolidated				
SEK Thousands	2023	2022	2023	2022	2023	2022	2023	2022			
North America	56 531	50 630	2 074	927	20 612	11 926	79 217	63 483			
South and Latin America	718	1 604	-	-	-	-	718	1 604			
EMEA	22 372	16 109	32 198	12 661	-	-	54 570	28 770			
Asia and Pacific	11 263	2 884	846	94	-	-	12 109	2 978			
Net sales	90 884	71 226	35 118	13 683	20 612	11 926	146 614	96 835			

Note 5. Goodwill

	January-	January-			January-
	September	September	July-September	July-September	December
TSEK	2023	2022	2023	2022	2022
Opening balance	625 319	460 228	653 469	498 213	460 228
Aquired goodwill	-	-	-	-	112 242
Exchange-rate differences	20 090	65 420	-8 060	27 435	52 849
Closing balance	645 409	525 648	645 409	525 648	625 319

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 2023	January- September 2022	July- September 2023	July- September 2022	January- December 2022
Operating income	20 311	4 105	5 302	-4 657	6 409
Depreciation and amortization on intangible assets	23 073	20 726	7 725	6 891	27 871
Depreciation and amortization on tangible assets	16 407	10 165	5 904	3 670	14 296
EBITDA (Operating income before depreciation and amortization)	59 791	34 996	18 931	5 904	48 576

EBITDA (adjusted)

SEK Thousands	January- September 2023	January- September 2022	July- September 2023	July- September 2022	January- December 2022
EBITDA (Operating income before depreciation and amortization)	59 791	34 996	18 931	5 904	48 576
Acquisition costs	-	3 963	-	3 963	8 146
Integration costs	21 625	3 955	9 055	195	6 102
Cash-based incentive programs for employees outside Europe	-	-6 279	-	-154	-6 372
EBITDA (adjusted)	81 416	36 635	27 986	9 908	56 452

EBIT (adjusted)

	January- September	January- September	July- September	July- September	January- December
SEK Thousands	. 2023	. 2022	. 2023	. 2022	2022
EBIT (Operating income)	20 311	4 105	5 302	-4 657	6 409
Acquisition costs	-	3 963	-	3 963	8 146
Integration costs	21 625	3 955	9 055	195	6 102
Cash-based incentive programs for employees outside Europe	-	-6 279	-	-154	-6 372
EBIT (adjusted)	41 936	5 744	14 357	-653	14 285

Gross margin

SEK Thousands	January- September 2023	January- September 2022	July- September 2023	July- September 2022	January- December 2022
Operating income					
Net sales	441 802	283 778	146 614	96 835	415 292
Operating expenses					
Cost of goods sold	-113 925	-81 679	-39 016	-27 464	-118 336
Gross income	327 877	202 099	107 598	69 371	296 956
Gross margin %	74	71	73	72	72

When calculating gross margin, gross profit is first calculated by subtracting the cost of goods sold from net sales. Gross profit is then set in relation to net sales to obtain the gross margin ratio. Gross margin thus indicates profit after cost of goods sold as a proportion of net sales, and is affected by factors such as pricing, raw materials and manufacturing costs, inventory write-downs and exchange rate effects.

Equity/Asset ratio

SEK Thousands	230930	220930	221231
Shareholders' equity	1 928 115	1 381 633	1 430 136
Total assets	2 237 108	1 641 499	1 733 084
Equity/assets ratio %	86	84	83

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	Justification for using key ratio
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.
Evaluation	Evaluation 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. An HDE is similar in both form and content to a Premarket Approval (PMA) application but is exempt from the efficacy requirements of a PMA.
Hypothermic non-ischemic perfusion of heart	Circulation of the cooled, dormant donated heart with a supply of oxygen and necessary nutrients during transport to the recipient.
Machine sales	Revenues from the sale or rental of machinery for mechanical perfusion and preservation of organs.
Clinical study/trial	A study in healthy or sick people to examine the effect of a drug or treatment method.
Machine perfusion	New technology that improves preservation and evaluation of organs, which means more organs can be used for transplants. In the Thoracic business area, this includes STEEN Solution™, XPS™, LS™, Lung Assist and Heart Assist as well as other products and services related to the use of those 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.
OPO or Organ Procurement Organization	In the United States, an organ procurement organization (OPO) is a non-profit organization responsible for the evaluation and procurement of deceased-donor organs for organ transplantation. There are approximately 58 such organizations in the United States.
Perfusion	Passage of a fluid through an organ's blood vessels.
PMA or Premarket Approval	Premarket Approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and efficacy of a medical device.
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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