


Report on Operations 2022

XVIVO Perfusion AB (publ)

XVIVO



Report on Operations 2022

Fourth quarter 2022 (October 1 - December 31)

- Net sales amounted to SEK 131.5 million (85.9), corresponding to an increase of 53 percent in SEK and 34 percent adjusted for currency effects. Organic growth accounted for 27 percent and acquired growth for 7 percent.
- All business areas delivered underlying growth adjusted for currency effects: Thoracic 26 percent, Abdominal 27 percent and Services 44 percent.
- The gross margin for disposables increased to 79 percent (77). The total gross margin was 72 percent (73).
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 15.6 million (-0.1) corresponding to an EBITDA margin of 10 percent (0). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 19.8 million (9.6), corresponding to an adjusted EBITDA margin of 15 percent (11).
- Operating income (EBIT) amounted to SEK 2.5 million (-8.5). Adjusted EBIT amounted to SEK 8.5 million (1.4).
- Net profit amounted to SEK 0.7 million (12.2). Earnings per share amounted to SEK 0.02 (0.42).
- Cash flow from operating activities increased to SEK 21.8 million (-0.6), a result of increased sales and positive EBITDA. Total cash flow amounted to SEK -58.1 million (111.2) and was primarily impacted by the initial purchase price for XVIVO S.r.l. of SEK -39.4 million, payment of the withheld portion of the purchase price for STAR Teams Inc. of SEK -7.0 million and investments in R&D projects of SEK -26.2 million.

Significant events during the quarter

- Positive results presented from the Australian and New Zealand heart preservation study.
- XVIVO completes the acquisition of the machine and perfusion business from its Italian distributor Avionord S.r.l.
- The new share issue directed at the shareholders of Avionord S.r.l. increased the number of shares and votes in XVIVO Perfusion AB (publ) by 269,952.
- XVIVO's Board of Directors appoints Christoffer Rosenblad as CEO.
- XVIVO strengthens its management team by appointing Lena Hagman as Chief Operating Officer, COO.

The period 2022 (January 1 - December 31)

- Net sales amounted to SEK 415.3 million (258.4), corresponding to an increase of 61 percent in SEK and 45 percent adjusted for currency effects. Organic growth accounted for 30 percent and acquired growth for 15 percent.
- All business areas delivered underlying growth adjusted for currency effects: Thoracic 32 percent, Abdominal 24 percent and Services 39 percent.
- The gross margin for disposables increased to 79 percent (76). The total gross margin was 72 percent (73).
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 48.6 million (13.8) corresponding to an EBITDA margin of 12 percent (5). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 56.5 million (29.5), corresponding to an adjusted EBITDA margin of 14 percent (11).
- Operating income (EBIT) amounted to SEK 6.4 million (-18.5). Adjusted operating income (EBIT) amounted to SEK 14.3 million (-2.7).
- Net profit increased to SEK 18.4 million (8.2). Earnings per share amounted to SEK 0.62 (0.28).
- Cash flow from operating activities increased to SEK 27.9 million (-12.1). Total cash flow amounted to SEK -176.6 million (34.8), and included a final additional purchase price payment relating to the acquisition of Organ Assist (XVIVIO B.V.) of SEK -21.0 million, an initial purchase price relating to XVIVO S.r.l. of SEK -39.4 million, payment of the withheld portion of the purchase price for STAR Teams Inc. of SEK -7.0 million and investments in R&D projects of SEK -111.6 million.

Significant events in the reporting period

- XVIVO's heart technology is used in the world's first ever successful heart xenotransplantation (pig to human)
- Kidney Assist Transport granted 510(k) clearance by the US FDA
- XVIVO obtains its first certificate under EU Medical Device Regulation (MDR) for Kidney Assist Transport
- An IDE application for the heart preservation study in the US was submitted to the FDA
- XVIVO gains regulatory approval in China for PERFADEX® Plus
- XVIVO signs an agreement to acquire 100 percent of the shares in Avionord S.r.l.'s machines and perfusion business - the company's distributor in Italy.
- Liver Assist granted a Breakthrough Device Designation by the US FDA
- XVIVO holds its second capital markets day
- XVIVO's CEO, Dag Andersson, passes away and Christoffer Rosenblad takes over as Acting CEO

Events after the end of the period

- The Board of Directors proposes that no dividend be paid for the 2022 financial year and that retained earnings be carried forward.

Key ratios

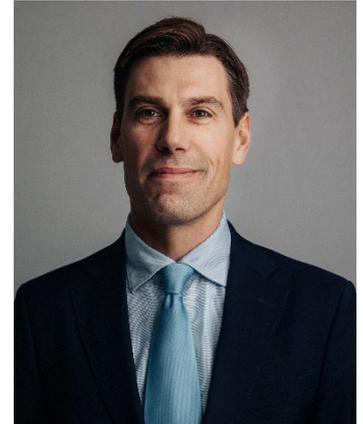
TSEK	January-December 2022	January-December 2021	October-December 2022	October-December 2021
Net sales	415 292	258 386	131 514	85 863
Gross margin, %	72	73	72	73
Gross margin disposables %	79	76	79	77
EBIT	6 409	-18 498	2 304	-8 300
EBIT (adjusted) ¹⁾	14 285	-2 716	8 541	1 361
EBITDA	48 576	13 759	13 580	-96
EBITDA (adjusted) ¹⁾	56 452	29 541	19 817	9 565
Cash flow from operating activities	27 856	-12 059	21 789	-562
Earnings per share, SEK	0.62	0.28	0.02	0.42
Changes in net sales				
Organic growth in local currency, %	30	27	27	32
Acquired growth, %	15	22	7	10
Currency effect, %	16	-5	19	-
Total growth, %	61	44	53	42

1) Adjusted for effect from cost provision attributable to cash-based incentive program for employees outside of Sweden, acquisition costs and integration costs. Net adjustment totals SEK -6.2 (-9.7) million for the quarter. Net adjustment for the period totals SEK -7.9 (-15.8) million.

CEO comment

Record quarter finishes a strong year

2022 was a strong year for XVIVO. Sales amounted to SEK 415 million (258) with organic growth of 30 percent in local currencies. The final fourth quarter testifies to a continued recovery of transplant activity worldwide and strong momentum for machine perfusion in particular. XVIVO's sales during the quarter set new records and totaled SEK 132 million (86). All of the business areas delivered strong growth, both year-on-year and sequentially.



Christoffer Rosenblad, CEO

Total sales in the quarter amounted to SEK 132 million (86), equivalent to growth of 53 percent. Organic growth amounted to 27 percent and acquired growth amounted to 7 percent.

Sales in the **Thoracic** business area amounted to SEK 88 million (59) – an increase of 49 percent year-on-year and an increase of 26 percent adjusted for currency effects. Machine perfusion constituted 50 percent (44) of sales. North America and Europe both had a strong finish to the year.

Abdominal delivered a strong quarter and it is pleasing that we are developing our leading position in liver transplantation in Europe. Sales amounted to SEK 27.4 million (20.6) in the quarter, which is equivalent to an increase of 33 percent year-on-year. Adjusted for currency effects, growth totaled 27 percent.

The **Services** business area, which includes our organ recovery service in the US, had organic growth of 44 percent due to new customer contracts during the quarter.

EBITDA margin for the quarter, adjusted for non-recurring costs such as acquisition costs, was 15 (11) percent. We continued to invest in our organization in order to support and accelerate our commercial and clinical plans.

On an operational level, the fourth quarter was eventful. The acquisition of Italian distributor XVIVO S.r.l, together with its machines and perfusion business, was completed on November 30. The Italian business model of combining technology with perfusion services is profitable and forges strong relationships with transplant clinics. I am confident that the company's leadership and former owner will contribute their valuable experience to XVIVO as we develop our service offering.

Another highlight during the quarter was that we followed up a successful XVIVO Masterclass Lung, held just over a year ago, with a by the customers highly appreciated XVIVO Masterclass Liver. Over 90 surgeons and opinion leaders from around the world participated and exchanged experiences with each other during the event hosted by XVIVO and its partners

In summing up 2022, it is clear that XVIVO has achieved several significant milestones during the year toward our goal of becoming the leading transplantation company for all major organs. We received 510(k) clearance from the FDA for Kidney Assist Transport in the US, the world's largest kidney transplantation market. Initial feedback from customers has been positive, and we are now ready to accelerate the launch in both the US and Europe in the first quarter of 2023. In the past year, XVIVO also received MDR certification for its entire abdominal product portfolio, which secures future sales opportunities in Europe.

In heart transplantation, XVIVO's technology facilitated two major clinical advances that have the potential to revolutionize the entire heart transplant field in the long term. The two advances are the groundbreaking first successful pig-to-human xenotransplantation, which took place in the US in early 2022, and the presentation of data from the heart preservation study in Australia and New Zealand with a focus on longer transport times. The study demonstrates that transport times of up to nine hours are possible with good clinical results, which is twice the current practice and recommended upper limit.

The strong finish to 2022 means we have the wind in our sails and self-confidence, and we are determined to make 2023 yet another successful year for XVIVO.

Christoffer Rosenblad, CEO

“The strong finish to 2022 means we have the wind in our sails and self-confidence”

This is XVIVO

Founded in 1998, XVIVO is the only medical technology company dedicated to extending the life of all major organs so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of transplantation medicine. XVIVO is headquartered in Gothenburg, Sweden, and has offices and research sites on two continents. The company is listed on Nasdaq Stockholm.

Vision

Nobody should die waiting for a new organ.

Purpose

We believe in an extended life for donated organs.

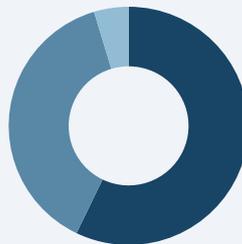
Target

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

>160.000

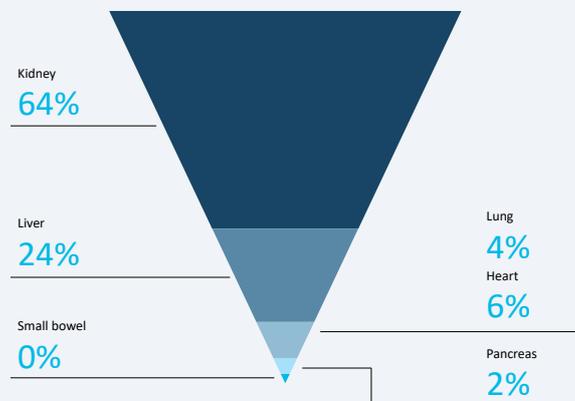
organs transplanted per year, representing ~10% of the need*

*WHO estimate



NET SALES PER GEOGRAPHICAL REGION IN THE QUARTER

■ Americas (57%)
■ EMEA (38%)
■ APAC (5%)



Strategic drivers

CUSTOMER-DRIVEN INNOVATION

To develop XVIVO commercially, we will bring innovation and progress even closer to our customers. Our established relationships with clinics, scientists and opinion leaders are an important asset in this context.

HIGH-PERFORMING ORGANIZATION

XVIVO has developed its leading research and development competences and capacity over many years. The next phase consists of building a more efficient organization to ensure the successful commercialization of our entire product portfolio.

COMMERCIAL POTENTIAL

XVIVO's commercial ability will be developed. Our active pricing strategy will be driven by clinical relevance and we will expand into new geographical markets.

OPERATIONAL STRENGTH

Our commercial potential is closely linked to our operational strength. A clearer operational focus will improve cost efficiency and delivery reliability.

Compilation of net sales and EBITDA

SEK Thousands	January-December 2022	January-December 2021	October-December 2022	October-December 2021
Net sales Thoracic	296 353	198 628	88 165	59 227
Net sales Abdominal	70 861	53 708	27 351	20 586
Net sales Services	48 078	6 050	15 998	6 050
Total Net sales	415 292	258 386	131 514	85 863
Gross income Thoracic	235 676	157 096	72 563	48 718
Gross margin Thoracic, %	80%	79%	82%	82%
Gross income Abdominal	37 733	27 982	14 730	11 071
Gross margin Abdominal, %	53%	52%	54%	54%
Gross income Services	23 547	3 201	7 564	3 201
Gross margin Services, %	49%	53%	47%	53%
Total Gross income	296 956	188 279	94 857	62 990
Total Gross margin, %	72%	73%	72%	73%
Selling expenses	-152 398	-97 216	-45 718	-34 974
Administrative expenses	-70 979	-55 687	-23 066	-21 095
Research and development expenses	-69 343	-54 039	-23 959	-15 476
Other operating revenues and expenses	2 173	165	190	255
Operating Income	6 409	-18 498	2 304	-8 300
Amortization and depreciation cost of goods sold	744	922	201	663
Depreciation administrative expenses	3 402	3 328	878	786
Amortization of research and development expenses	31 024	23 085	8 088	5 630
Depreciation other operative expenses	6 997	4 922	2 109	1 125
EBITDA (Operating income before depreciation and amortization)	48 576	13 759	13 580	-96
EBITDA, %	12%	5%	10%	0%
EBITDA (adjusted) 1)	56 452	29 541	19 817	9 565
EBITDA (adjusted), %	14%	11%	15%	11%

1) Adjusted for effect from cost provision attributable to cash-based incentive program for employees outside of Sweden, acquisition costs and integration costs. Net adjustment totals SEK -6.2 (-9.7) million for the quarter. Net adjustment for the period totals SEK -7.9 (-15.8) million.

New segment reporting as of 2022

From January 1, 2022 new segment reporting was introduced to better reflect the company's operative business segments which are a result of business acquisitions in the last two years. The new segments are Thoracic, Abdominal and Services and correspond with the Group's business areas. Furthermore, names have been changed as follows; the new name for durable goods is "machines" and the new name for non-durable goods is "disposables". For further information about segments, see Note 4.

Summary

The quarter October - December 2022

Net sales and income

Sales in the quarter amounted to SEK 131.5 million (85.9), equivalent to growth of 53 percent year-on-year. The organic growth was 27 percent, acquired growth was 7 percent and the remaining 19 percent constituted currency effects. All business areas demonstrated solid growth, adjusted for currency effects. For a description of development within each business area, see pages 12-13.

The total gross margin for the quarter was 72 percent (73). We are pleased to report that the gross margin for disposables in the Thoracic business area once again increased year-on-year, driven by price increases and a strengthening of the US dollar. Thoracic's margin for disposables increased to 85 percent (83). For comments regarding margins in each business area, see pages 12-13.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 13.6 million (-0.1) corresponding to an EBITDA margin of 10 percent (0). EBITDA was positively affected by the reversal of a provision for cash-based incentive programs for employees outside Sweden of SEK 0.1 million and was also affected by integration costs of SEK -2.1 million and acquisition costs of SEK -4.2 million. Adjusting for these items totaling SEK -6.2 million (-9.7), EBITDA amounted to SEK 19.8 million (9.6), corresponding to an adjusted EBITDA margin of 15 percent (11).

Operating income (EBIT) amounted to SEK 2.3 million (-8.3). EBIT adjusted for the aforementioned costs amounted to SEK 8.5 million (1.4).

Selling expenses in relation to sales amounted to 35 percent (41) for the quarter. R&D expenses amounted to 18 percent (18) of sales. Administrative expenses amounted to 18 percent (25).

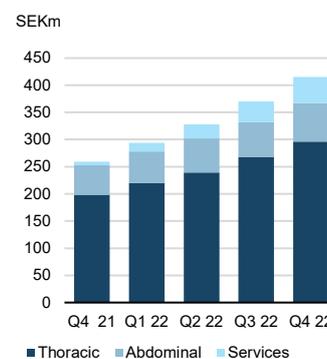
Capitalization and amortization

During the quarter, SEK 26.2 million (28.5) 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 6.8 million (5.0) in the quarter.

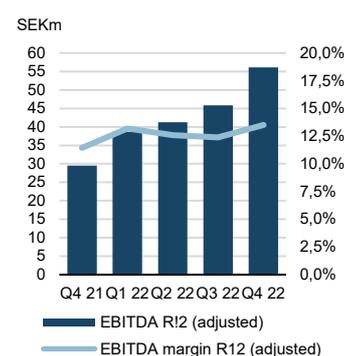
Cash flow

Cash flow from operating activities increased by SEK 4.8 million compared to the third quarter of the year and totaled SEK 21.8 million (-0.6), primarily due to increased sales and positive EBITDA. Cash flow from investing activities amounted to SEK -77.1 million (-125.2), of which SEK -7.0 million related to an additional purchase price in relation to the acquisition of STAR and SEK -39.4 million related to a net cash payment for the acquisition of XVIVO S.r.l. Furthermore, SEK -26.4 million (-28.8) was invested in intangible assets and SEK -4.1 million (-3.1) in tangible assets. Cash flow from financing activities amounted to net SEK -2.8 million (236.9). Cash and cash equivalents at the end of the quarter amounted to SEK 246.5 million (398.7).

Net sales per business area (R12)



EBITDA and EBITDA margin (adjusted, R12)



Significant events during the quarter

Positive results presented from the heart preservation study in Australia and New Zealand

The Australian and New Zealand investigator-initiated Multicenter Trial of Extended (6-8 hours) Non-Ischemic Heart Preservation (NIHP) of Donor Hearts for Transplantation included five hospitals and the last patient was given a transplant during the fourth quarter. The study was led by Professor David Kaye and Professor David McGiffin from The Alfred in Melbourne.

Professor David Kaye presented his experiences from the study, which focuses on, among other things, longer transport times for donated hearts, at the American Heart Association (AHA) 2022 conference in Chicago. The impressive results show that there was no mortality in the first 20 patients in the study to receive a donated heart preserved using XVIVO's heart technology, despite the considerably prolonged transport times, which were up to 8 hours and 47 minutes.

XVIVO completes the acquisition of the machine and perfusion business from Avionord S.r.l.

On November 30, 2022, XVIVO completed the acquisition of all shares in XVIVO S.r.l., whose machine and perfusion business was transferred from Avionord S.r.l. through a so-called carve-out. The initial purchase price consisted of a cash payment of EUR 4.2 million (approximately 40 percent of the initial purchase price) and newly issued shares in XVIVO at a value of SEK 60.1 million (approximately 60 percent of the initial purchase price). A potential earn-out of a maximum of EUR 2.4 million may be paid in 2023. Costs attributable to the acquisition totaled SEK 8.4 million and were recognized as Administrative expenses in the Group Income Statement in 2022.

Avionord S.r.l. was XVIVO's Italian distributor and the acquisition strengthens XVIVO's European presence while broadening its service offering with the aim of further accelerating the establishment of machine perfusion. The Italian operation initially includes six employees, including management.

The acquisition of Avionord M&P supports XVIVO's strategy of becoming the preferred partner in the transplant process. XVIVO has already established a service offering on the US market in connection with the acquisition of STAR Teams in fall 2021. STAR Teams provides US transplant clinics with services relating to organ recovery.

XVIVO appoints a new CEO

XVIVO appoints Christoffer Rosenblad as CEO.

XVIVO strengthens its management team

XVIVO is continuing to build and strengthen the organization. Lena Hagman, with many years' experience from Getinge, was appointed Chief Operating Officer, COO.

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 269,952 in December 2022 as a result of the new share issue in relation to the acquisition of XVIVO S.r.l. As of December 31, 2022, there were a total of 29,831,919 shares and votes in the company.

The period January - December 2022

Net sales and income

Sales in the period amounted to SEK 415.3 million (258.4), equivalent to growth of 61 percent year-on-year. The increase comprised organic growth of 30 percent, acquired growth of 15 percent and the remaining 16 percent related to currency effects.

All business areas delivered underlying growth adjusted for currency effects: Thoracic 32 percent, Abdominal 24 percent and Services 39 percent. The growth in Thoracic and Abdominal was primarily due to increased sales volumes and price increases. In Services, the growth primarily relates to new customer contracts compared to the equivalent period in the previous year.

The gross margin for disposables increased in the period year-on-year. The margins in Thoracic and Abdominal were 84 percent (81) and 54 percent (53) respectively, driven by the price increases implemented across all markets during the year. The margin in Thoracic also benefited from a strong US dollar.

The total gross margin for the period was 72 percent (73). The reduction was due to increased machine sales in Thoracic combined with the addition of the Service business area compared to the previous period. For comments regarding the margins in each business area, see pages 12-13.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 48.6 million (13.8) corresponding to an EBITDA margin of 12 percent (5). EBITDA was positively affected by the reversal of a provision for cash-based incentive programs for employees outside Sweden of SEK 6.4 million and was also affected by integration costs of SEK -6.1 million and acquisition costs of SEK -8.2 million. Adjusting for these items totaling SEK -7.9 million (-15.8), EBITDA amounted to SEK 56.5 million (29.5), corresponding to an adjusted EBITDA margin of 14 percent (11).

Operating income (EBIT) amounted to SEK 6.4 million (-18.5). EBIT adjusted for the aforementioned costs amounted to SEK 14.3 million (-2.7).

Selling expenses as a proportion of sales amounted to 37 percent (38) for the period. R&D expenses amounted to 17 percent (21) of sales. The decrease was primarily due to a larger proportion of the expenses being capitalized in development projects year-on-year. Administrative expenses amounted to 17 percent (22) of sales.

Capitalization and amortization

During the period, SEK 111.6 million (81.0) 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 26.4 million (20.0) in the period.

Cash flow

Cash flow from operating activities increased to SEK 27.9 million (-12.1), primarily due to increased sales and positive EBITDA. Cash flow from investing activities amounted to SEK -197.6 million (-187.7), of which SEK -21.0 million related to the final additional purchase price payment in relation to the acquisition of Organ Assist (XVIVO B.V), SEK -7.0 million related to payment of the withheld portion of the purchase price for STAR Teams Inc and SEK -59.4 million related to the net cash payment for the acquisition of XVIVO S.r.l. Furthermore, SEK -112.8 million (-83.9) was invested in intangible assets and SEK -18.2 million (-10.2) in tangible assets. Cash flow from financing activities amounted to net SEK -6.8 million (234.6). Cash and cash equivalents at the end of the period amounted to SEK 246.5 million (398.7).

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 83 percent (85) 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 415
million**

Gross margin

72%

Adjusted EBITDA

14%

Significant events in the reporting period

XVIVO's heart technology was used in the world's first ever successful heart xenotransplantation (pig to human)

On January 7, 2022, the world's first ever successful pig-to-human heart transplant took place, a groundbreaking milestone in the field of organ transplants. A team at the University of Maryland School of Medicine, the US, performed the procedure. After retrieval, the pig heart was preserved using XVIVO's heart perfusion device and patent protected solution until transplanted. The patient was a 57-year-old terminally ill man and he lived for two months with the transplanted pig heart. One of the biggest challenges in transplantation is the shortage of organs. Xenotransplantation, transplantation between species, presents a potential solution to the critical organ shortage.

XVIVO's Kidney Assist Transport granted 510(k) clearance by the US FDA

In January 2022, the US Food & Drug Administration (FDA) granted clearance for Kidney Assist Transport – a transportable organ perfusion system for kidneys with unique technology that allows for continuous oxygenated perfusion for up to 24 hours. The advantages of the technology over technology currently available on the market were highlighted in *The Lancet* journal in December 2020.¹ A pre-launch of Kidney Assist Transport began in the US during the second quarter and Kidney Assist Transport has been presented at key trade fairs in both the US and Europe.

XVIVO obtained its first certificate under EU Medical Device Regulation (MDR) for Kidney Assist Transport

In the first quarter, an important milestone was reached when XVIVO B.V. received EU MDR certification for Kidney Assist Transport. This signifies that XVIVO B.V.'s quality management system, and the corresponding abdominal perfusion product, meet the requirements of the new EU Medical Device Regulation (MDR). The new Medical Device Regulation (MDR) came into force in 2017 and is applicable since May 26, 2021.

XVIVO gained regulatory approval in China for PERFADEX® Plus

XVIVO Perfusion AB has gained regulatory approval in China from NMPA (National Medical Products Administration) for the company's 'ready-to-use' product PERFADEX Plus. China is the second largest transplant market in the world. It is also currently the fastest growing lung transplant market with an average annual growth rate of 28 percent during the six-year period 2015-2020.

An IDE application for the heart preservation study in the US was submitted to the US FDA

In the second quarter, XVIVO filed an Investigational Device Exemption (IDE) application to the US Food & Drug Administration (FDA). The application seeks approval for conducting: "PRESERVE Clinical Trial: A Prospective, Multi-center, Single-Arm, Open-Label Study of Hearts Transplanted after Non-Ischemic Heart PRESERVation from Extended Donors" with XVIVO's heart technology for machine perfusion, which will lay the basis for an application for Premarket Approval (PMA). The FDA responded to the application and XVIVO is currently in the process of submitting additional documentation in accordance with the FDA's responses.

Entered into partnership with the Cleveland Clinic for advanced analytics of perfusion data

XVIVO and the Cleveland Clinic in the US have entered into a partnership in advanced analytics, XPS Live, using lung perfusion data from XVIVO's XPS machines. Extracted data from lung perfusion procedures will be analyzed as aggregated data to provide significant insight into, for example, so-called marginal lungs where the uncertainty regarding the quality of these organs is high. The long-term goal for XPS Live is to create a data-driven model based on data from all XPS machines globally.

XVIVO granted a Breakthrough Device Designation by the FDA for its Liver Assist

XVIVO has been granted a Breakthrough Device Designation by the US Food and Drug Administration (FDA) for its Liver Assist technology. Liver Assist is indicated for oxygenated machine perfusion for the preservation of donor livers ex vivo prior to transplantation. An article published in *The New England Journal of Medicine* last year shows that oxygenated hypothermic perfusion of DCD donor livers before transplantation has a significant positive impact on post-transplant clinical outcomes.²

XVIVO presented a strategy for 2023-2027 at the capital markets day

XVIVO held its capital markets day in September. The company's updated strategy for the period 2023-2027 is based on five focus areas: 1) Becoming market leader in Abdominal; 2) Leading the paradigm shift in heart preservation; 3) Becoming the preferred partner in the transplant process; 4) Accelerating market leadership in lungs; and 5) New market expansion. XVIVO's growth will be supported by several significant growth drivers and the company expects to further strengthen its gross margins, primarily driven by significant increases in margins in the Abdominal business area. XVIVO is sharpening its profitability ambitions and shall achieve an EBIT margin of at least 20 percent and an EBITDA margin of at least 30 percent during the strategy period.

The CEO of XVIVO, Dag Andersson, passed away

The CEO of XVIVO, Dag Andersson, passed away suddenly in September. The Board decided that Christoffer Rosenblad, the former Deputy CEO of XVIVO, would be Acting CEO until a successor had been appointed. Upon preparing a clear job specification for the role, the Board found that Christoffer Rosenblad met the specified requirements. Christoffer Rosenblad was appointed the new CEO on November 30, 2022.

¹ [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32411-9/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32411-9/fulltext)

² <https://www.nejm.org/doi/full/10.1056/NEJMoa2031532>

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 269,952 in December 2022 as a result of the new share issue in relation to the acquisition of XVIVO S.r.l. As of December 31, 2022, there were a total of 29,831,919 shares and votes in the company.

The number of shares and votes in XVIVO Perfusion AB (publ) also changed in June 2022. As a result of the utilization of warrants under the company's incentive scheme 2020/2022, the number of shares and votes increased by 63,301.

Business area development

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

Thoracic

The Thoracic business area consists of XVIVO's lung and heart transplantation business. In lung transplantation, the company's product Perfadex® Plus has a market share of approximately 90 percent in traditional static preservation of lungs. The company's products for warm perfusion, XPS™ and STEEN Solution™, have 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. Some sales take place in heart transplantation – mainly to pre-clinical xenotransplantation projects.

Summary

SEK Thousands	January-December 2022	January-December 2021	October-December 2022	October-December 2021
Net sales	296 353	198 628	88 165	59 227
Disposables	276 589	192 063	84 753	58 929
Machines	19 764	6 565	3 412	298
Gross margin, %	80	79	82	82
Disposables	84	81	85	83
Machines	15	30	8	7

The quarter October - December 2022

Thoracic delivered a strong fourth quarter. Sales amounted to SEK 88.2 million (59.2) – equivalent to growth of 49 percent year-on-year or 26 percent adjusted for currency effects.

The momentum we experienced in EVLP in the first three quarters continued during the fourth quarter. An XPS machine was delivered to a hospital in France during the quarter.

Machine perfusion accounted for 50 percent (44) of net sales, which was due to increased EVLP activity. Static preservation and other sales accounted for the remainder of net sales.

The gross margin for disposables increased to 85 percent (83). The improved margin compared to the previous quarter is primarily due to the price increases carried out and currency effects from a strong US dollar.

The period January - December 2022

Sales increased by 49 percent in the period compared to the corresponding period in the previous year and amounted to SEK 296.4 million (198.6). The increase is equivalent to an increase of 32 percent adjusted for currency effects.

Sales of disposables increased by 44 percent in the period, amounting to SEK 276.6 million (192.1). Adjusted for currency effects, this represented growth of 26 percent.

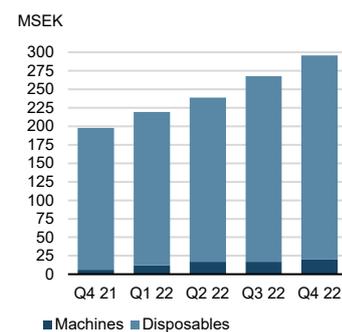
The number of lung transplantations performed in the US, for example, in 2022 was in line with 2019 – the year before the pandemic. Having said that, XVIVO's growth in recent years has primarily come from increased EVLP volumes and price increases.

In total, nine new XPS machines were installed in 2022 – four in the US and five in Europe. Demand is expected to continue to increase.

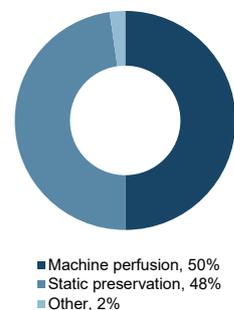
Machine perfusion accounted for 50 percent (41) of net sales. Static preservation and other sales accounted for the remainder of net sales.

The gross margin for disposables increased to 84 percent (81). The improved margin compared to the previous period is primarily due to the price increases carried out and currency effects from a strong US dollar.

Net sales Thoracic (R12)



Net sales per product category Thoracic (Q4)



Abdominal

The Abdominal business area consists of XVIVO's product and service operations in liver and kidney transplantation. XVIVO offers oxygenated machine perfusion products for both organs. In 2022, products for liver and kidney transplants were primarily sold in selected markets in Europe, but also in other smaller markets. During the fourth quarter, XVIVO acquired XVIVO S.r.l, the company's distributor on the Italian market. The acquisition enables XVIVO to add perfusion services to its product offering on the important Italian market.

Summary

SEK Thousands	January-December 2022	January-December 2021	October-December 2022	October-December 2021
Net sales	70 861	53 708	27 351	20 586
Disposables	59 877	41 908	21 923	15 029
Machines	10 984	11 800	5 428	5 557
Gross margin, %	53	52	54	54
Disposables	54	53	54	55
Machines	51	50	52	50

The quarter October - December 2022

Sales amounted to SEK 27.4 million (20.6) in the quarter, which is equivalent to an increase of 33 percent year-on-year. Adjusted for currency effects, growth totaled 27 percent. The increase for disposables was strong at 50 percent, or 37 percent adjusted for currency effects. The revenue was primarily generated in Europe and approximately 70 percent related to liver perfusion.

The gross margin for disposables was on a par with last year at 54 percent (55).

The period January - December 2022

Sales in the period amounted to SEK 70.9 million (53.7), equivalent to growth of 32 percent year-on-year. Adjusted for currency effects, growth totaled 24 percent. The increase for disposables was strong at 43 percent, or 34 percent adjusted for currency effects.

The gross margin for disposables was on a par with the previous year at 54 percent (55). The margin is expected to increase in 2023 as a result of price increases, the introduction of Kidney Assist Transport and the combined product and service offering in Italy.

Services

The Services business area comprises STAR Teams' organ recovery operations 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 are pioneers on the US market and provide around fifteen US thoracic clinics with their services. The company was acquired on November 9, 2021.

Summary

SEK Thousands	January-December 2022	January-December 2021	October-December 2022	October-December 2021
Net sales	48 078	6 050	15 998	6 050
Gross margin, %	49	53	47	53

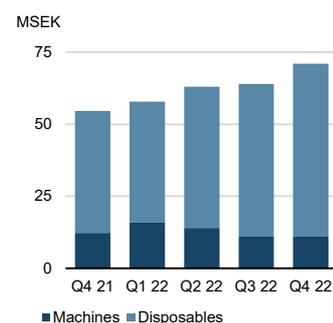
The quarter October - December 2022

STAR Teams' sales experienced organic growth of 44 percent year-on-year, primarily driven by an increased customer base of thoracic clinics. Four new contracts were secured during the fourth quarter. The gross margin was 47 percent and is expected to increase as the customer base expands and economies of scale are generated.

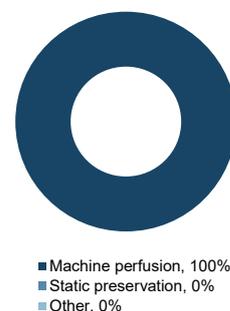
The period January - December 2022

Sales growth was 39 percent year-on-year. STAR Teams increased the number of organ recoveries by 23 percent year-on-year and was responsible for a total of 495 organ recoveries during the year. The gross margin for the full year was 49 percent.

Net sales Abdominal (R12)



Net sales per product category, Abdominal (Q4)



Organs recovered in 2022

495

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 period when a donated heart can survive outside the body. In collaboration with Professor Stig Steen, XVIVO has developed a comprehensive solution consisting of fluids and machinery that better preserve the function of the donated heart during transport, which contributes to improved outcomes after heart transplantation as well as enabling longer transport. In the ongoing clinical trials, the results from the transplants of donated hearts transported using XVIVO's method are evaluated and compared to the conventional ice-box method.</p>	<p>XVIVO has a program of clinical multicenter studies. These will form the basis for applications for regulatory approval for the products on all major markets worldwide. In Europe, fifteen clinics now actively include patients in XVIVO's study. The initial experiences reported by the users of the technology have been positive. A multicenter study is in the final planning phase in the US. The company has submitted an IDE application and is currently working closely with the FDA.</p> <p>In addition to the studies conducted by XVIVO, researcher-initiated clinical studies with XVIVO's technology are ongoing in Lund and Australia. The latter presented excellent interim data at the biggest US conference for cardiologists (AHA) in November 2022. The data came from transplantations performed using XVIVO technology with transport times of up to almost nine hours. The complete study data will be presented at the 2023 Annual Meeting & Scientific Sessions of the ISHLT.</p> <p>An additional number of pre-clinical initiatives are underway or have been started by leading researchers within heart transplantation.</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 perfusion improves post-transplant outcomes.</p>	<p>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 solutions is the focus of research in the field of organ transplantation.</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 oxygenated perfusion of a liver before transplantation reduces the risk of serious complications in many cases.</p>	<p>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). Further investigator-driven studies using XVIVO's technology are ongoing and the suitability of the technology in different clinical environments is being investigated. The combination of new perfusion technology and optimized solutions will be the focus of future research in the field.</p>
 <p>PrimECC®</p>	<p>PrimECC® is a fluid developed in collaboration with Professor Stig Steen intended for use in heart-lung machines. Before connecting the heart-lung machine to a patient, it must be filled with fluid, usually simple saline solutions. In 2016 and 2017, a randomized clinical trial on 80 patients indicated reduced side effects related to the use of heart-lung machines when using PrimECC®.</p>	<p>XVIVO has patents for PrimECC® in the key markets the US, EU, China, and Japan. Several hundred thousand heart surgeries are performed each year, which means considerable sales potential if good clinical outcomes can be demonstrated. The company will carry out a product launch once the results from the ongoing study in Sweden, Denmark and Germany are available. Several new German centers are in the start-up phase.</p>

Research projects

Project	Description	Status
 <p>Xenotransplantation</p>	<p>Xenotransplantation involves the use of non-human organs in transplantation. The method is currently at the research stage for several organs.</p>	<p>The first successful transplantation to a human was performed in January 2022, attracting significant media attention. 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 within xenotransplantation.</p>

Other information

Sustainability

Everyone who works at XVIVO is dedicated to our vision that “nobody should die waiting for a new organ” and we are proud that our innovations help give patients the opportunity to live longer and better lives. For more than two decades we have focused on developing, manufacturing and marketing technology that contributes to making more donated organs available for transplant.

XVIVO’s Code of Conduct is our primary sustainability policy. It includes guidelines for business principles, human rights and working principles. For more detailed information relating to our sustainability work, see the company’s Annual Report for 2021. Our key policies are also available at www.xvivogroup.com.

Organization and staff

The XVIVO Group has 133 employees, of whom 59 are women and 74 men. Of these, 49 are employed in Sweden and 84 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

In 2022, the Group’s former CEO invoiced the company SEK 225,000 for the letting of his apartment to one of the Group’s employees. The rental agreement, which is based on market terms, expired in the third quarter. Otherwise, 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 operative risks for the Group can be found in the administration report as part of the Annual Report for 2021, which is available at www.xvivogroup.com.

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
Caroline Sjösten, appointed by Swedbank Robur Fonder AB
Gösta Johannesson, Chairman of the Board

The above have been 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 32.7 percent of all shares in the company on August 31, 2022.

Annual General Meeting and Annual Report

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on April 25, 2023 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), Att: The Nomination Committee, Box 53015, SE-400 14 Gothenburg 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 2022 is expected to be available to download from the XVIVO website in the week beginning April 3, 2023.

Dividend

The Board of Directors proposes that no dividend be paid for the 2022 financial year and that retained earnings be carried forward.

Outlook

XVIVO starts 2023 with the wind in its sails from a positive 2022. We see continued growing interest in our product and service offering across all organ areas. The commercial focus will continue to be on increasing the installed base and the use of our leading perfusion technologies. As of the first quarter of 2023, we look forward to being able to accelerate the introduction of Kidney Assist Transport on the world's largest kidney transplant markets: the US and Europe.

The goal for the next six months is to include the final patients in the European heart preservation study. The aim is still to launch our heart technology in Europe in the first quarter of 2024. The study in Australia/New Zealand included its final patient during the fourth quarter of 2022, and discussions are in progress with the participating clinics about the best way that XVIVO can support their work in 2023 pending product approval. We are engaged in positive dialog with the FDA regarding the heart study in the US and we intend to plan for the start of the study as soon as the FDA allows. As a result of the increased focus on regulatory studies and product launches, we will continue to invest in our organization, primarily in our main market in the US.

Although XVIVO and the transplantation industry in general are making significant progress, there is of course 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. Manufacturing takes place either in Western Europe or the US. Accordingly, we do not judge that the war in Ukraine is having any direct negative impact on the company's operations at present.

The extent to which the Covid-19 pandemic will affect XVIVO's sales and clinical trials in 2023 remains largely dependent on whether the intensive care operations in our main markets in the US and Europe have returned to normal. The vast majority of markets are undergoing a recovery, which bodes well for continued positive development for XVIVO and for transplantation operations worldwide.

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.

Gothenburg, January 26, 2023

Gösta Johannesson
Chairman of the Board

Camilla Öberg
Board member

Göran Dellgren
Board member

Yvonne Mårtensson
Board member

Lars Henriksson
Board member

Lena Höglund
Board member

Christoffer Rosenblad
CEO

This 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 26, 2023 at 7.30 am CET.



Financial calendar

- Interim Report January-March 2023: Monday, April 24, 2023
- Annual General Meeting: Tuesday April 25, 2023
- Interim Report January-June 2023: Thursday, July 13, 2023
- Interim Report January-September 2023: Tuesday, October 24, 2023
- Year-End Report 2023: Thursday, January 25, 2024



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 Thursday January 26, 2023.

To register and obtain a PIN code for the event, click [here](#)

To access the digital presentation live event, click [here](#)



Contact

Christoffer Rosenblad, CEO
tel: +46 735 19 21 59
email: christoffer.rosenblad@xvivogroup.com

Kristoffer Nordström, CFO
tel: +46 735 19 21 64
email: kristoffer.nordstrom@xvivogroup.com

Financial statements

Condensed Consolidated Statement of Net Income

SEK Thousands	January-December 2022	January-December 2021	October-December 2022	October-December 2021
Net sales	415 292	258 386	131 514	85 863
Cost of goods sold	-118 336	-70 107	-36 657	-22 873
Gross income	296 956	188 279	94 857	62 990
Selling expenses	-152 398	-97 216	-45 718	-34 974
Administrative expenses	-70 979	-55 687	-23 066	-21 095
Research and development expenses	-69 343	-54 039	-23 959	-15 476
Other operating revenues and expenses	2 173	165	190	255
Operating income	6 409	-18 498	2 304	-8 300
Financial income and expenses	15 905	25 163	447	18 537
Income after financial items	22 314	6 665	2 751	10 237
Taxes	-3 887	1 487	-2 017	1 952
Net income	18 427	8 152	734	12 189
Attributable to				
Parent Company's shareholders	18 427	8 152	734	12 189
Earnings per share, SEK	0.62	0.28	0.02	0.42
Earnings per share, SEK ¹⁾	0.62	0.28	0.02	0.41
Average number of outstanding shares	29 525 946	28 845 691	29 602 717	29 241 732
Average number of outstanding shares ¹⁾	29 525 946	28 936 075	29 602 717	29 615 732
Number of shares at closing day	29 831 919	29 498 666	29 831 919	29 498 666
Number of shares at closing day ¹⁾	29 831 919	29 872 666	29 831 919	29 872 666
EBITDA (Operating income before depreciation and amortization)	48 576	13 759	13 580	-96
Depreciation and amortization on intangible assets	-27 871	-21 219	-7 145	-5 336
Depreciation and amortization on tangible assets	-14 296	-11 038	-4 131	-2 868
Operating income	6 409	-18 498	2 304	-8 300

¹⁾ After dilution

Consolidated Statement of Total Comprehensive Income

SEK Thousands	January-December 2022	January-December 2021	October-December 2022	October-December 2021
Net income	18 427	8 152	734	12 189
Other comprehensive income				
Items that may be reclassified to the income statement				
Exchange rate differences	65 693	22 271	-12 173	15 394
Total other comprehensive income	65 693	22 271	-12 173	15 394
Total comprehensive income	84 120	30 423	-11 439	27 583
Attributable to				
Parent Company's shareholders	84 120	30 423	-11 439	27 583

Condensed Consolidated Statement of Financial Position

SEK Thousands	221231	211231
ASSETS		
Goodwill	625 319	460 228
Capitalized development expenditure	544 510	456 551
Other intangible fixed assets	8 484	8 658
Fixed assets	47 579	26 297
Financial assets	39 684	43 330
Total non-current assets	1 265 576	995 064
Inventories	106 566	77 590
Current receivables	114 397	71 246
Liquid funds	246 545	398 696
Total current assets	467 508	547 532
Total assets	1 733 084	1 542 596
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity, attributable to the Parent Company's shareholders	1 430 136	1 285 450
Long-term interest-bearing liabilities	4 455	1 522
Long-term non-interest-bearing liabilities	163 597	151 105
Short-term interest-bearing liabilities	5 550	4 199
Short-term non-interest-bearing liabilities	129 346	100 320
Total shareholders' equity and liabilities	1 733 084	1 542 596

Condensed Consolidated Cash Flow Statements

	January-December 2022	January-December 2021	October-December 2022	October-December 2021
Income after financial items	22 314	6 665	2 751	10 237
Adjustment for items not affecting cash flow	27 510	7 195	14 209	-5 087
Paid taxes	199	-2 701	1 791	-496
Change in inventories	-6 325	-13 802	-10 534	-896
Change in trade receivables	-26 860	-8 294	-7 647	-12 825
Change in trade payables	11 018	-1 122	21 219	8 505
Cash flow from operating activities	27 856	-12 059	21 789	-562
Cash flow from investing activities	-197 624	-187 703	-77 054	-125 158
Cash flow from financing activities	-6 842	234 611	-2 800	236 895
Cash flow for the period	-176 610	34 849	-58 065	111 175
Liquid funds at beginning of period	398 696	354 236	314 561	284 516
Exchange rate difference in liquid funds	24 459	9 611	-9 951	3 005
Liquid funds at end of period	246 545	398 696	246 545	398 696

Consolidated Changes in Shareholders' Equity

SEK Thousands	Attributable to Parent Company's shareholders				Sum shareholders' equity
	Share capital	Other paid in capital	Reserves	Retained earnings incl. profit for the year	
Shareholders' equity as of January 1, 2021	734	1 006 784	-183	1 126	1 008 461
Total comprehensive income January - December 2021	-	-	22 271	8 152	30 423
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	20	245 307	-	-	245 327
Share warrant program	-	1 239	-	-	1 239
Shareholders' equity as of December 31, 2021	754	1 253 330	22 088	9 278	1 285 450
Total comprehensive income January - December 2022	-	-	65 693	18 427	84 120
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	8	59 694	-	49	59 751
Share warrant program	-	815	-	-	815
Shareholders' equity as of December 31, 2022	762	1 313 839	87 781	27 754	1 430 136

Condensed Consolidated Statement of Net Income per quarter

SEK Thousands	Oct-Dec 2022	Jul-Sep 2022	Apr-Jun 2022	Jan-Mar 2022	Oct-Dec 2021	Jul-Sep 2021	Apr-Jun 2021	Jan-Mar 2021
Net sales	131 514	96 835	94 289	92 654	85 863	54 935	59 263	58 325
Cost of goods sold	-36 657	-27 464	-26 783	-27 432	-22 873	-16 977	-15 009	-15 248
Gross income	94 857	69 371	67 506	65 222	62 990	37 958	44 254	43 077
Selling expenses	-45 718	-39 387	-37 774	-29 519	-34 974	-23 530	-22 975	-15 737
Administrative expenses	-23 066	-18 734	-14 779	-14 400	-21 095	-9 049	-14 856	-10 687
Research and development costs	-23 959	-16 651	-12 075	-16 658	-15 476	-10 428	-14 988	-13 147
Other operating revenues and expenses	190	744	1 260	-21	255	1 018	-785	-323
Operating income	2 304	-4 657	4 138	4 624	-8 300	-4 031	-9 350	3 183
Financial income and expenses	447	7 649	6 244	1 565	18 537	2 956	-1 411	5 081
Income after financial items	2 751	2 992	10 382	6 189	10 237	-1 075	-10 761	8 264
Taxes	-2 017	2 406	-2 852	-1 424	1 952	-54	1 820	-2 231
Net income	734	5 398	7 530	4 765	12 189	-1 129	-8 941	6 033
Attributable to								
Parent Company's shareholders	734	5 398	7 530	4 765	12 189	-1 129	-8 941	6 033
Earnings per share, SEK	0.02	0.18	0.26	0.16	0.42	-0.04	-0.31	0.21
Earnings per share, SEK ¹⁾	0.02	0.18	0.26	0.16	0.41	-0.04	-0.31	0.20
Average number of outstanding shares	29 602 717	29 512 733	29 512 733	29 498 666	29 241 732	28 727 266	28 727 266	28 719 136
Average number of outstanding shares ¹⁾	29 602 717	29 512 733	29 512 733	29 872 666	29 615 732	29 101 266	29 101 266	29 444 136
Number of shares at closing day	29 831 919	29 561 967	29 561 967	29 498 666	29 498 666	28 752 397	28 752 397	28 719 136
Number of shares at closing day ¹⁾	29 831 919	29 561 967	29 561 967	29 872 666	29 872 666	29 126 397	29 126 397	29 444 136
EBITDA (Operating income before depreciation and amortization)	13 580	5 904	14 399	14 693	-96	4 181	-1 533	11 207
Depreciation and amortization on intangible assets	-7 145	-6 891	-6 929	-6 906	-5 336	-5 278	-5 135	-5 470
Depreciation and amortization on tangible assets	-4 131	-3 670	-3 332	-3 163	-2 868	-2 934	-2 682	-2 554
Operating income	2 304	-4 657	4 138	4 624	-8 300	-4 031	-9 350	3 183

¹⁾ After dilution

Consolidated Statement of Total Comprehensive Income per quarter

SEK Thousands	Oct-Dec 2022	Jul-Sep 2022	Apr-Jun 2022	Jan-Mar 2022	Oct-Dec 2021	Jul-Sep 2021	Apr-Jun 2021	Jan-Mar 2021
Net income	734	5 398	7 530	4 765	12 189	-1 129	-8 941	6 033
Other comprehensive income								
Items that may be reclassified to the income statement:								
Exchange rate differences	-12 173	30 381	37 862	9 623	15 394	3 163	-3 704	7 418
Total other comprehensive income	-12 173	30 381	37 862	9 623	15 394	3 163	-3 704	7 418
Total comprehensive income	-11 439	35 779	45 392	14 388	27 583	2 034	-12 645	13 451
Attributable to								
Parent Company's shareholders	-11 439	35 779	45 392	14 388	27 583	2 034	-12 645	13 451

Consolidated Key Ratios

SEK Thousands	January-December 2022	January-December 2021	October-December 2022	October-December 2021
Gross margin, %	72	73	72	73
Gross margin disposables, %	79	76	79	77
EBIT, %	2	-7	2	-10
EBIT (adjusted), %	3	-1	6	2
EBITDA, %	12	5	10	-
EBITDA (adjusted), %	14	11	15	11
Net margin, %	4	3	1	14
Equity/assets ratio, %	83	83	83	83
Income per share, SEK	0.62	0.28	0.02	0.42
Shareholders' equity per share, SEK	47.94	43.58	47.94	43.58
Share price on closing day, SEK	183	279	183	279
Market cap on closing day, MSEK	5 459	8 230	5 459	8 230

Condensed Income Statement for the Parent Company

SEK Thousands	January-December 2022	January-December 2021	October-December 2022	October-December 2021
Net sales	243 737	161 287	70 867	36 940
Cost of goods sold	-54 599	-30 757	-17 397	-6 259
Gross income	189 138	130 530	53 470	30 681
Selling expenses	-59 489	-52 486	-14 079	-19 232
Administrative expenses	-55 691	-39 907	-15 885	-9 215
Research and development expenses	-52 355	-45 372	-15 021	-11 501
Other operating revenues and expenses	2 324	-125	424	265
Operating income	23 927	-7 360	8 909	-9 002
Financial income and expenses	19 982	6 475	2 019	-1 345
Income after financial items	43 909	-885	10 928	-10 347
Taxes	-9 177	-181	-2 173	2 794
Net income	34 732	-1 066	8 755	-7 553

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 19,133 (19,360) thousand, of which SEK 4,729 (4,777) thousand in the quarter.

Condensed Balance Sheet for the Parent Company

SEK Thousands	221231	211231
ASSETS		
Intangible fixed assets	363 398	292 229
Property, plant and equipment	10 775	8 980
Financial assets	926 531	719 916
Total non-current assets	1 300 704	1 021 125
Inventories	27 548	21 805
Current receivables	36 890	25 258
Cash and bank	196 281	369 479
Total current assets	260 719	416 542
Total assets	1 561 423	1 437 667
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity	1 341 567	1 246 317
Provisions	1 374	1 499
Long-term non-interest-bearing liabilities	137 130	124 522
Short-term non-interest-bearing liabilities	81 352	65 329
Total shareholders' equity and liabilities	1 561 423	1 437 667

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 361 million (470) and SEK 102 million (78) 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 170.4 million (150.7) relating to additional purchase prices linked to acquisitions. Additional purchase prices 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 21.5 million (1.3) 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	221231	211231
Opening balance	150 676	40 150
Additional purchase considerations	26 224	129 650
Reversal of additional purchase considerations	-	-20 454
Payment of additional purchase considerations	-27 999	-
Exchange-rate differences	21 515	1 330
Closing balance	170 416	150 676

Note 3. Net sales

Distribution of net sales

SEK Thousands	January-December							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
Disposables	276 589	192 063	59 877	41 908	-	-	336 466	233 971
Machines	19 764	6 565	10 984	11 800	-	-	30 748	18 365
Services	-	-	-	-	48 078	6 050	48 078	6 050
Net sales	296 353	198 628	70 861	53 708	48 078	6 050	415 292	258 386

SEK Thousands	October-December							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
Disposables	84 753	58 929	21 923	15 029	-	-	106 676	73 958
Machines	3 412	298	5 428	5 557	-	-	8 840	5 855
Services	-	-	-	-	15 998	6 050	15 998	6 050
Net sales	88 165	59 227	27 351	20 586	15 998	6 050	131 514	85 863

Net sales by geographical area

SEK Thousands	January-December							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
North America	188 284	126 211	8 912	1 831	48 078	6 050	245 274	134 092
South and Latin America	5 086	3 541	-	1 032	-	-	5 086	4 573
EMEA	89 920	56 811	56 118	49 527	-	-	146 039	106 338
Asia and Pacific	13 062	12 066	5 831	1 317	-	-	18 893	13 383
Net sales	296 353	198 628	70 861	53 708	48 078	6 050	415 292	258 386

SEK Thousands	October-December							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
North America	55 880	39 114	2 473	-	15 998	6 050	74 351	45 164
South and Latin America	816	1 724	-	-	-	-	816	1 724
EMEA	28 796	15 459	21 423	20 458	-	-	50 218	35 917
Asia and Pacific	2 674	2 930	3 456	129	-	-	6 129	3 058
Net sales	88 165	59 227	27 351	20 586	15 998	6 050	131 514	85 863

Note 4. Consolidated operating segments

From January 1, 2022 new segment reporting was introduced to better reflect the company's operative business segments which are a result of two business acquisitions in recent years. The new 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	
	2022	2021	2022	2021	2022	2021	2022	2021
Net sales	296 353	198 628	70 861	53 708	48 078	6 050	415 292	258 386
Cost of goods sold	-60 677	-41 532	-33 128	-25 726	-24 531	-2 849	-118 336	-70 107
Gross income	235 676	157 096	37 733	27 982	23 547	3 201	296 956	188 279
Gross margin (%)	80	79	53	52	49	53	72	73

SEK Thousands	October-December							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
Net sales	88 165	59 227	27 351	20 586	15 998	6 050	131 514	85 863
Cost of goods sold	-15 602	-10 509	-12 621	-9 515	-8 434	-2 849	-36 657	-22 873
Gross income	72 563	48 718	14 730	11 071	7 564	3 201	94 857	62 990
Gross margin (%)	82	82	54	54	47	53	72	73

Note 5. Business acquisitions

STAR Teams Inc.

On November 9, 2021, XVIVO acquired 100 percent of the shares and votes in the US organ recovery company STAR Teams Inc. The acquisition took place for a cash purchase price of up to USD 26.1 million with an initial payment of USD 12.3 million and a potential additional purchase price of up to USD 13.8 million. The additional purchase price is paid out provided that a combination of revenue and gross margin targets are met in 2023. In the event that the targets are not met in 2023, a recovery period begins, where the additional purchase price is instead based on a combination of revenue and gross margin targets in 2024.

STAR Teams is a pioneer and the leading US operator in organ recovery, consisting of a team with more than 15 years of clinical experience that, at the time of acquisition, had successfully recovered more than 1,200 organs in the US states where it is based. At present, STAR Teams is active in the field of lung and heart organs and plans to expand to kidney and liver organs. The expansion is in line with XVIVO's strategy of becoming a global provider of solutions and systems for all major organs.

The acquisition analysis, which was a preliminary analysis in 2022, was completed in connection with the annual financial statements for December 31. 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 client as well as increased sales potential for new clients, which can be achieved by utilizing XVIVO's knowledge and experience within marketing and established networks for the acquired operations. Synergies that could create future sales values are also to be found within research and development, in particular information and product development.

The table below presents the final acquisition analysis.

SEK Thousands	Fair Value
Purchase price	
Paid purchase price	94 618
Holdback	10 784
Conditional additional purchase price	112 408
Total	217 810
Acquired net assets	
Intangible assets	-
Accounts receivable and other receivables	5 946
Liquid funds	1 390
Accounts payable and other payables	-9 857
Fair value of acquired net assets	-2 521
Goodwill	220 331
Total	217 810
Impact on the Group's cash flow	
Purchase price, initial payment in cash	94 618
Less: Cash and cash equivalents in acquired company	-1 390
Impact on the Group's cash and cash equivalents during 2021	93 228

XVIVO S.r.l.

On November 30, 2022, XVIVO acquired 100 percent of the shares in Avionord S.r.l.'s machine and perfusion business, which was transferred to the new start-up XVIVO S.r.l. The initial purchase price consisted of a cash payment of EUR 4.2 million (approximately 40 percent of the initial purchase price) and newly issued shares in XVIVO at a value of SEK 60.1 million (approximately 60 percent of the initial purchase price). A potential earn-out of a maximum of EUR 2.4 million may be paid in 2023. The additional purchase price will be paid out provided that an EBITDA target for the operation in 2022 is met.

Costs attributable to the acquisition totaled SEK 8.4 million and were recognized as Administrative expenses in the Group Income Statement in 2022. In 2022, XVIVO S.r.l. contributed SEK 5.3 million to Group revenue and SEK 0.9 million to Group profit.

Avionord S.r.l. was XVIVO's Italian distributor and approximately 90 percent of its revenue is generated from organ perfusion machines purchased from XVIVO. The acquisition strengthens XVIVO's European presence while broadening its service offering with the aim of further accelerating the establishment of machine perfusion. The Italian operation initially includes six employees, including management.

The acquisition analysis as of 31 December 2022 is still preliminary and will be completed during 2023. Goodwill primarily consists of synergy effects such as greater profitability per customer and increased sales potential for new customers. The table below presents the initial, preliminary acquisition analysis*.

SEK Thousands	Fair Value
Purchase price	
Paid purchase price	45 889
Issuing of new shares	60 071
Conditional additional purchase price	26 224
Total	132 184
Acquired net assets *	
Intangible assets	146
Fixed assets	4 829
Inventory	5 532
Accounts receivable and other receivables	10 937
Liquid funds	6 442
Accounts payable and other payables	-7 944
Fair value of acquired net assets	19 942
Goodwill	112 242
Total	132 184
Impact on the Group's cash flow	
Purchase price, initial payment in cash	45 889
Less: Cash and cash equivalents in acquired company	-6 442
Impact on the Group's cash and cash equivalents during 2022	39 447

* Work to finish a complete valuation of the identified, acquired intangible assets is underway. Accordingly, the acquisition analysis will be adjusted when the fair values of acquired intangible assets have been determined. This valuation will be completed in 2023.

Reconciliation of alternative performance measures

This report includes key figures 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 ratios as a complement to, rather than a substitute for, financial information under IFRS.

EBITDA

	January-December 2022	January-December 2021	October-December 2022	October-December 2021
SEK Thousands				
Operating income	6 409	-18 498	2 304	-8 300
Depreciation and amortization on intangible assets	27 871	21 219	7 145	5 336
Depreciation and amortization on tangible assets	14 296	11 038	4 131	2 868
EBITDA (Operating income before depreciation and amortization)	48 576	13 759	13 580	-96

EBITDA (adjusted)

	January-December 2022	January-December 2021	October-December 2022	October-December 2021
SEK Thousands				
EBITDA (Operating income before depreciation and amortization)	48 576	13 759	13 580	-96
Acquisition costs	8 146	13 350	4 183	9 956
Integration costs	6 102	6 334	2 147	513
Cash-based incentive programs for employees outside Europe	-6 372	-3 902	-93	-808
EBITDA (adjusted)	56 452	29 541	19 817	9 565

EBIT (adjusted)

	January-December 2022	January-December 2021	October-December 2022	October-December 2021
SEK Thousands				
EBIT (Operating income)	6 409	-18 498	2 304	-8 300
Acquisition costs	8 146	13 350	4 183	9 956
Integration costs	6 102	6 334	2 147	513
Cash-based incentive programs for employees outside Europe	-6 372	-3 902	-93	-808
EBIT (adjusted)	14 285	-2 716	8 541	1 361

Gross profit margin

	January-December 2022	January-December 2021	October-December 2022	October-December 2021
SEK Thousands				
Operating income				
<i>Net sales</i>	415 292	258 386	131 514	85 863
Operating expenses				
<i>Cost of goods sold</i>	-118 336	-70 107	-36 657	-22 873
Gross income	296 956	188 279	94 857	62 990
Gross margin %	72	73	72	73

When calculating the 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. The gross margin thus indicates the proportion of net sales converted into profit after deducting cost of goods sold.

Equity/assets ratio

	221231	211231
SEK Thousands		
Shareholders' equity	1 430 136	1 285 450
Total assets	1 733 084	1 542 596
Equity/assets ratio %	83	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 for 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 translating the period's and previous period's sales in local currencies into Swedish kronor 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:

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 refers to 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.



XVIVO
Box 53015
SE-400 14 Gothenburg
Sweden

info@xvivogroup.com
www.xvivogroup.com