


Interim Report January - September 2022

XVIVO Perfusion AB (publ)

XVIVO



Interim Report January - September 2022

Third quarter 2022 (July 1 - September 30)

- Net sales amounted to SEK 96.8 million (54.9), corresponding to an increase of 76 percent in SEK and 57 percent adjusted for currency effects. Organic growth accounted for 35 percent and acquired growth for 22 percent.
- All business areas delivered underlying organic growth adjusted for currency effects: Thoracic 45 percent, Abdominal 1 percent (but 32 percent for disposables) and Services 22 percent.
- The gross margin for disposables increased to 79 percent (75). The total gross margin was 72 percent (69).
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 5.9 million (4.2) corresponding to an EBITDA margin of 6 percent (8). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 9.9 million (5.3), corresponding to an adjusted EBITDA margin of 10 percent (10).
- Operating income (EBIT) amounted to SEK -4.7 million (-4.0). Adjusted EBIT amounted to SEK -0.7 million (-2.9).
- Net profit increased to SEK 5.4 million (-1.1). Earnings per share amounted to SEK 0.18 (-0.04).
- Cash flow from operating activities increased to SEK 17.0 million (-8.5), a result of increased sales and less capital tied up in operating receivables. Total cash flow amounted to SEK -18.4 million (-30.0) after investments in R&D projects of SEK -27.9 million.

Significant events during the quarter

- 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. The acquisition is expected to be completed in the fourth quarter.
- 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

Key ratios

	January-September 2022	January-September 2021	July-September 2022	July-September 2021	Full year 2021
TSEK					
Net sales	283 778	172 523	96 835	54 935	258 386
Gross margin, %	71	73	72	69	73
Gross margin disposables %	79	75	79	73	76
EBIT	4 105	-10 198	-4 657	-4 031	-18 498
EBIT (adjusted) ¹⁾	5 744	-4 077	-653	-2 906	-2 716
EBITDA	34 996	13 855	5 904	4 181	13 759
EBITDA (adjusted) ¹⁾	36 635	19 976	9 908	5 306	29 541
Cash flow from operating activities	6 067	-11 497	16 971	-8 455	-12 059
Earnings per share, SEK	0,60	-0,14	0,18	-0,04	0,28
Changes in net sales					
Organic growth in local currency, %	32	24	35	-	27
Acquired growth, %	18	30	22	30	22
Currency effect, %	14	-10	19	-2	-5
Total growth, %	64	44	76	29	44

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 -4.0 (-1.1) million for the quarter. Net adjustment for the period totals SEK -1.6 (-6.1) million.

The period 2022 (January 1 - September 30)

- Net sales amounted to SEK 283.8 million (172.5), corresponding to an increase of 64 percent in SEK and 50 percent adjusted for currency effects. Organic growth accounted for 32 percent and acquired growth for 18 percent.
- All business areas delivered underlying organic growth adjusted for currency effects: Thoracic 34 percent, Abdominal 22 percent and Services 37 percent.
- The gross margin for disposables increased to 79 percent (75). The total gross margin was 71 percent (73) due to the segment mix.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 35.0 million (13.9) corresponding to an EBITDA margin of 12 percent (8). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 36.6 million (20.0), corresponding to an adjusted EBITDA margin of 13 percent (12).
- Operating income (EBIT) amounted to SEK 4.1 million (-10.2). Adjusted operating income (EBIT) amounted to SEK 5.7 million (-4.1).
- Net profit increased to SEK 17.7 million (-4.0). Earnings per share amounted to SEK 0.60 (-0.14).
- Cash flow from operating activities increased to SEK 6.1 million (-11.5). Total cash flow amounted to SEK -118.5 million (-76.3), and included a final additional purchase consideration payment relating to the acquisition of Organ Assist (XVIVIO B.V.) of SEK -21.0 million and R&D investments of SEK -85.4 million.

Significant events in the reporting period

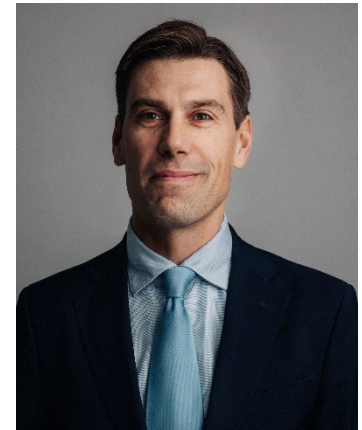
- XVIVO's heart technology is used in the world's first ever successful heart xenotransplantation (pig to human)
- Kidney Assist Transport granted 510(k) clearance by the US FDA
- XVIVO obtains its first certificate under EU Medical Device Regulation (MDR) for Kidney Assist Transport
- An IDE application for the heart preservation study in the US was submitted to the FDA
- XVIVO gains regulatory approval in China for PERFADEX® Plus

CEO comment

Our strategy remains unchanged

A month ago, XVIVO's CEO Dag Andersson suddenly passed away. Our thoughts are with Dag's family. A strong management team and organization have been established over the past two years. We are ready to deliver in line with the strategy presented at our capital markets day in September.

Our path forward over the next few years is clear: We shall be the world-leader in organ transplantation. XVIVO has developed unique, innovative and world-leading products that put us in a very strong market position.



Christoffer Rosenblad, Acting CEO

The third quarter got off to a promising start with the acquisition of the machines and perfusion business from our Italian distributor, Avionord. The acquisition, which is expected to be completed in the fourth quarter, represents an important milestone for XVIVO as we are now able to introduce our first service offering in Europe. The service model drives penetration of the machine perfusion sector and is therefore fully in line with our set strategy. The acquisition will also improve our gross margins considerably on our biggest abdominal market, Italy, because Avionord's unique business model combines products and services with good profitability, as well as cutting a chain in the distribution link.

The **Thoracic** business area remained strong in the third quarter. Sales amounted to SEK 71 million (42), equivalent to growth of 45 percent adjusted for currency effects. Momentum for machine perfusion (EVLP) is continuing, as demonstrated by the delivery of a further three XPS machines during the quarter. What is particularly interesting is that one of these XPS machines was delivered to a transplant clinic in Oklahoma, which, in collaboration with Cleveland Clinic, is now starting a new EVLP program. The aim is to create a regional EVLP hub that will serve several of the US states in the long run. Thoracic's gross margin increased to 81 percent (75).

In the **Abdominal** business area, sales of the strategically important disposables, adjusted for currency effects, increased by 32 percent year-on-year. Total sales amounted to SEK 14 million (13), which is equivalent to an increase of 8 percent and 1 percent adjusted for currency effects. The change in growth is a natural result of the strategic machine placements without initial revenue. The launch of Kidney Assist Transport is expected to be able to accelerate at the beginning of next year after we have increased the production capacity of machines.

Adjusted EBITDA was 10 percent (10) in the quarter. If we also adjust for organizational non-recurring costs, EBITDA amounted to 14 percent, which is a clear increase on the comparison quarter.

We are continuing to hear very positive noises from our heart preservation studies. Our dialog with the US FDA regarding our IDE application before the start of the study in the US is continuing to move in a positive direction. The European study is continuing to include patients at a good rate and the investigator-initiated study in Australia/New Zealand is expected to include its last patient during the fourth quarter. The confidence shown by the Australian surgeons in our heart technology fills us with enthusiasm - XVIVO's heart technology has the potential to lead to a paradigm shift in heart transplantation.

During the quarter we were delighted to announce that we have been granted a Breakthrough Designation for Liver Assist by the US FDA. The designation not only recognizes that the technology has a high rate of innovation but also that it fulfills an important need on the US market. Preparations for a PMA study will now begin. Liver Assist was also granted MDR clearance during the quarter, which enables sales to continue in the European market.

On September 21, we held our second capital markets day. Over 100 current and potential shareholders took part in the digital event where we presented our updated strategy that will help XVIVO become world-leading in organ transplantation. We have a clear plan for how we will become a leader in Abdominal, maintain and grow our world-leading lung business while increasing our service offering more clearly to support our customers effectively. Over our five-year strategy period we will also grow on new markets and bring our unique heart technology to market.

We have presented three strong quarters in 2022 and look forward to finishing off the year in the same spirit. XVIVO has earned a reputation for presenting growth while being profitable and we shall continue as before.

Christoffer Rosenblad, Acting CEO

“We have presented three strong quarters in 2022 and look forward to finishing the year in the same spirit.”

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.

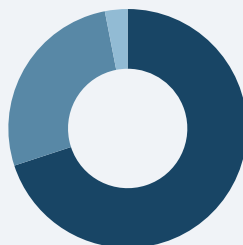
Target

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

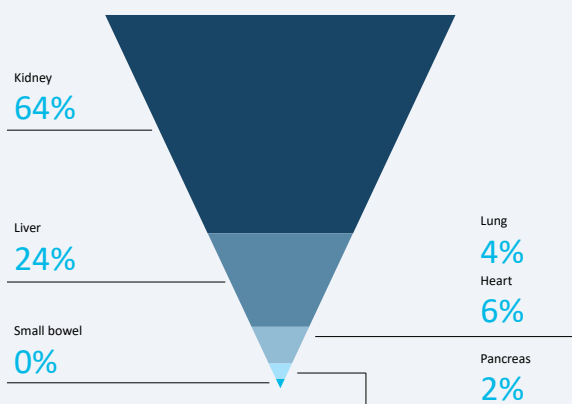


NET SALES PER GEOGRAPHICAL REGION IN THE QUARTER

- Americas (70%)
- EMEA (27%)
- APAC (3%)

~98%

of the market is covered by XVIVO's total offering



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 formers are an important asset in this context.

HIGH-PERFORMING ORGANIZATION

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

COMMERCIAL POTENTIAL

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

OPERATIONAL STRENGTH

Our commercial potential is closely 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-September 2022	January-September 2021	July-September 2022	July-September 2021	January-December 2021
Net Sales Thoracic	208 188	138 558	71 226	42 270	198 628
Net Sales Abdominal	43 510	33 965	13 683	12 665	53 708
Net Sales Services	32 080	-	11 926	-	6 050
Net Sales Total	283 778	172 523	96 835	54 935	258 386
Gross income Thoracic	163 113	107 942	57 528	31 651	157 096
Gross margin Thoracic, %	78%	78%	81%	75%	79%
Gross income Abdominal	23 003	17 347	6 516	6 307	27 982
Gross margin Abdominal, %	53%	51%	48%	50%	52%
Gross income Services	15 983	-	5 327	-	3 201
Gross margin Services, %	50%	-	45%	-	53%
Gross income Total	202 099	125 289	69 371	37 958	188 279
Gross margin Total, %	71%	73%	72%	69%	73%
Selling expenses	-106 680	-62 242	-39 387	-23 530	-97 216
Administrative expenses	-47 913	-34 592	-18 734	-9 049	-55 687
Research and development expenses	-45 384	-38 563	-16 651	-10 428	-54 039
Other operating revenues and expenses	1 983	-90	744	1 018	165
Operating Income	4 105	-10 198	-4 657	-4 031	-18 498
Amortization and depreciation cost of goods sold	543	259	180	90	922
Depreciation administrative expenses	2 524	2 542	849	896	3 328
Amortization of research and development expenses	22 936	17 455	7 655	5 894	23 085
Depreciation other operative expenses	4 888	3 797	1 877	1 332	4 922
EBITDA (Operating income before depreciation and amortization)	34 996	13 855	5 904	4 181	13 759
EBITDA, %	12%	8%	6%	8%	5%
EBITDA (adjusted) 1)	36 635	19 976	9 908	5 306	29 541
EBITDA (adjusted), %	13%	12%	10%	10%	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 -4.0 (-1.1) million for the quarter. Net adjustment for the period totals SEK -1.6 (-6.1) 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 July - September 2022

Net sales and income

Sales in the quarter amounted to SEK 96.8 million (54.9), equivalent to growth of 76 percent year-on-year. The organic growth was 35 percent, acquired growth was 22 percent and the remaining 19 percent constituted currency effects. All business areas demonstrated underlying organic growth in their core business, adjusted for currency effects. For a description of development within each business area, see pages 10-11.

The total gross margin increased to 72 percent (69) in the quarter. 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 84 percent (78). For comments regarding margins in each business area, see pages 10-11.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 5.9 million (4.2) corresponding to an EBITDA margin of 6 percent (8). EBITDA was positively affected by the reversal of a provision for cash-based incentive programs for employees outside Sweden of SEK 0.2 million and was also affected by integration costs of SEK -0.2 million and acquisition costs of SEK -4.0 million. Adjusting for these items totaling SEK -4.0 million (-1.1), EBITDA amounted to SEK 9.9 million (5.3), corresponding to an adjusted EBITDA margin of 10 percent (10). If we also exclude organizational non-recurring costs of SEK 4 million, EBITDA was 14 percent for the quarter.

Operating income (EBIT) amounted to SEK -4.7 million (-4.0). EBIT adjusted for the aforementioned costs amounted to SEK -0.7 million (-2.9).

Selling expenses in relation to sales amounted to 40 percent (43) for the quarter and include SEK 2.0 million of organizational non-recurring costs. R&D expenses amounted to 17 percent (19) of sales. Administrative expenses amounted to 19 percent (16) of sales and include SEK 6.0 million of non-recurring costs.

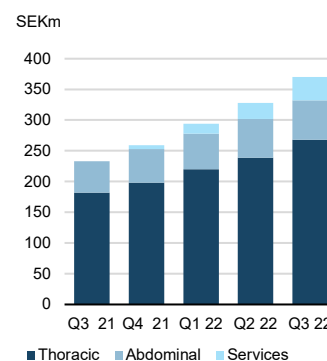
Capitalization and amortization

During the quarter, SEK 27.9 million (18.0) 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 6.5 million (5.0) in the quarter.

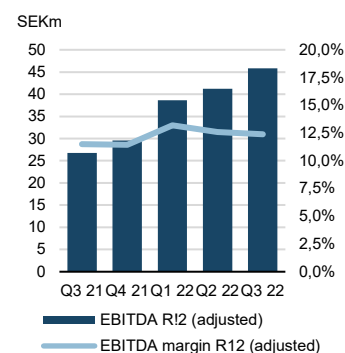
Cash flow

Cash flow from operating activities increased by SEK 18.5 million compared to the second quarter of the year and totaled SEK 17.0 million (-8.5), primarily due to increased sales, a positive EBITDA and less capital tied up in accounts receivable. Cash flow from investing activities amounted to SEK -33.7 million (-20.2), of which SEK -28.0 million (-18.0) was invested in intangible assets and SEK -6.1 million (-1.9) was invested in tangible assets. Cash flow from financing activities amounted to net SEK -1.6 million (-1.4). Cash and cash equivalents at the end of the quarter amounted to SEK 314.6 million (284.5).

Net sales per business area (R12)



EBITDA and EBITDA margin (adjusted, R12)



Significant events during the quarter

XVIVO signed an agreement to acquire part of Avionord

XVIVO signed an agreement to acquire 100 percent of the shares in Avionord S.r.l.'s machine and perfusion business (M&P) for a purchase consideration of up to EUR 12.0 million. The initial purchase consideration is a maximum of EUR 9.6 million, of which approximately 40 percent is to be paid in cash and 60 percent through newly issued shares in XVIVO. There is also a potential additional purchase consideration of up to EUR 2.4 million to be paid in 2023.

The third quarter has been burdened by acquisition costs of SEK 4 million, otherwise the acquisition has not generated any additional revenues or costs. The acquisition and related new share issue are expected to be completed in the fourth quarter 2022.

Avionord M&P is XVIVO's Italian distributor and approximately 90 percent of its revenues 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 new legal entity will be called XVIVO S.r.l. and will initially have six employees, including the management team.

The acquisition of Avionord M&P supports XVIVO's strategy to become the natural choice of partner in the transplant process. XVIVO has previously established a service offering on the American market in connection with the acquisition of STAR Teams in the fall of 2021. STAR Teams provides American transplant clinics with services in organ recovery.

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.¹

The FDA's Breakthrough Device Program aims to accelerate and prioritize the regulatory review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

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 Perfusion, Dag Andersson, passed away

The CEO of XVIVO Perfusion AB (publ), Dag Andersson, suddenly passed away. The Board decided that Christoffer Rosenblad, the former Deputy CEO of XVIVO, will be Acting CEO until a successor has been appointed.

¹ <https://www.nejm.org/doi/full/10.1056/NEJMoa2051532>

The period January - September 2022

Net sales and income

Sales in the period amounted to SEK 283.8 million (172.5), equivalent to growth of 64 percent year-on-year. The increase comprised organic growth of 32 percent, acquired growth of 18 percent and the remaining 14 percent related to currency effects.

All business areas delivered underlying organic growth adjusted for currency effects: Thoracic 34 percent, Abdominal 22 percent and Services 37 percent. The growth in Thoracic and Abdominal was primarily due to increased sales volumes and price increases. In Services, the growth relates to additional customer contracts compared to the equivalent period in the previous year.

The gross margin for disposables in Thoracic and Abdominal increased year-on-year. The margins in Thoracic and Abdominal were 84 percent (80) and 53 percent (51) respectively, driven by the price increases implemented across all markets in the fourth quarter of 2021 (US) and in the first quarter of 2022 (Europe and the rest of the world). The margin in Thoracic also benefited from a strong US dollar.

The total gross margin for the period was 71 percent (73). The reduction was due to an increased proportion of machine sales in Thoracic and Abdominal 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 10-11.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 35.0 million (13.9) corresponding to an EBITDA margin of 12 percent (8). EBITDA was positively affected by the reversal of a provision for cash-based incentive programs for employees outside Sweden of SEK 6.3 million and was also affected by integration costs of SEK -3.9 million and acquisition costs of SEK -4.0 million. Adjusting for these items totaling SEK -1.6 million (-6.1), EBITDA amounted to SEK 36.6 million (20.0), corresponding to an EBITDA margin of 13 percent (12). If we also exclude organizational non-recurring costs of SEK 4 million during the third quarter, EBITDA was 14 percent for the period.

Operating income (EBIT) amounted to SEK 4.1 million (-10.2). EBIT adjusted for the aforementioned costs amounted to SEK 5.7 million (-4.1).

Selling expenses as a proportion of sales amounted to 37 percent (36) for the period. The increased selling expenses for the period were mainly due to an upturn in sales activity as a result of the pandemic abating, investments in the sales organization as well as organizational non-recurring costs. R&D expenses amounted to 16 percent (22) 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 (20) of sales but include SEK 6 million of non-recurring costs. Excluding these costs, they amount to 14 percent of sales.

Capitalization and amortization

During the period, SEK 85.4 million (55.1) of development expenses were capitalized as intangible assets. Development expenses essentially relate to expenses for R&D projects with the aim of obtaining regulatory approvals in the US and Europe. Amortization of capitalized development expenditure amounted to SEK 19.6 million (15.9) in the period.

Cash flow

Cash flow from operating activities was SEK 6.1 million (-11.5) in the period. The positive effect of increased sales and strong EBITDA was diminished by increased capital tied up, mainly in accounts receivable. The situation is expected to improve during the fourth quarter in line with increased payments from customers. Cash flow from investing activities amounted to SEK -120.6 million (-62.5), of which SEK -21.0 million related to the final additional purchase consideration payment in relation to the acquisition of Organ Assist (XVIVO B.V). Furthermore, SEK -86.4 million (-55.1) was invested in intangible assets and SEK -14.1 million (-7.1) in tangible assets. Cash flow from financing activities amounted to net SEK -4.0 million (-2.3). Cash and cash equivalents at the end of the period amounted to SEK 314.6 million (284.5).

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 84 percent (88) at the end of the period. The company's total credit facility consists of an overdraft facility, which amounted to SEK 30 million (30) at the end of the period, of which SEK 0.0 million (0.0) was utilized.

Net sales

**SEK 284
million**

Gross margin

71%

Adjusted EBITDA

13%

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 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 2020.² The pre-launch of Kidney Assist Transport began in the US during the second quarter with Northwestern in Illinois and the Mayo Clinic in Florida being the first clinics to receive the technology. During the year, Kidney Assist Transport was presented at key industry conferences in both the US and Europe and clinics have shown strong interest.

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 has gained regulatory approval in China from the NMPA (National Medical Products Administration) for its 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. In 2020, 513 lung transplants were performed. Due to the increased need, the number of clinics authorized to perform lung transplants has grown from 20 in 2016 to 50 in 2021.

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.

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 63,301 shares and votes in June 2022 as a result of warrants being utilized under the company's incentive scheme 2020/2022. As of June 30, 2022, there were a total of 29,561,967 shares and votes in the company.

² [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)52411-9/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)52411-9/fulltext)

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-September 2022	January-September 2021	July-September 2022	July-September 2021
Net sales	208 188	138 558	71 226	42 270
Disposables	191 836	132 748	69 188	39 940
Machines	16 352	5 810	2 038	2 330
Gross margin, %	78	78	81	75
Disposables	84	80	84	78
Machines	17	34	-40	20

The quarter July - September 2022

Thoracic once again delivered a strong quarter. Sales amounted to SEK 71.2 million (42.3) – equivalent to growth of 69 percent year-on-year or 45 percent adjusted for currency effects.

The number of lung transplantations performed in the US, for example, still does not show any growth but is in line with 2019 – the year before the pandemic. Having said that, our growth in recent years has primarily come from increased EVLP volumes and price increases. The momentum we experienced in EVLP in the first and second quarters continued in the third quarter. Two XPS machines were installed in the US and one in Italy.

Machine perfusion accounted for 51 percent (38) 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 84 percent (78). 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 - September 2022

Sales increased by 50 percent in the period compared to the corresponding period in the previous year and amounted to SEK 208.2 million (138.6). The increase is equivalent to an increase of 34 percent adjusted for currency effects.

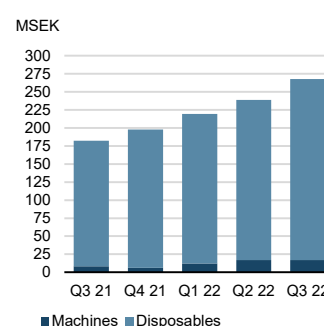
Sales of disposables increased by 45 percent in the period, amounting to SEK 191.8 million (132.7). Adjusted for currency effects, this represented growth of 28 percent.

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

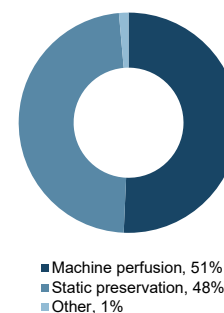
Machine perfusion accounted for 49 percent (40) of net sales. Static preservation and other sales accounted for the remainder of net sales.

The gross margin for disposables increased to 84 percent (80). 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 (Q3)



Abdominal

The Abdominal business area consists of XVIVO's operations in liver and kidney transplantation. XVIVO offers oxygenated machine perfusion products for both organs. Products for liver and kidney transplants are primarily sold in selected markets in Europe, but also in other smaller markets. During the second quarter of 2022, Kidney Assist Transport - XVIVO's first abdominal product to receive clearance for clinical sales in the US - was pre-launched in the US, the world's largest kidney market.

Summary

SEK Thousands	January-September 2022	January-September 2021	July-September 2022	July-September 2021
Net sales	43 510	33 965	13 683	12 665
Disposables	37 954	27 265	12 640	8 953
Machines	5 556	6 700	1 043	3 712
Gross margin, %	53	51	48	50
Disposables	53	51	51	53
Machines	49	50	9	42

The quarter July - September 2022

Sales amounted to SEK 13.7 million (12.7) in the quarter, which is equivalent to an increase of 8 percent year-on-year. The increase for disposables was very strong at 41 percent, or 32 percent adjusted for currency effects. Total growth adjusted for currency effects was 1 percent, which is due to the decrease in machine revenue compared to the previous quarter. During the quarter, a larger proportion of the machines were delivered without initial revenue. During the comparison quarter, the machines were sold to a greater extent. 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 51 percent (53).

The period January - September 2022

Sales in the period amounted to SEK 43.5 million (34.0), equivalent to growth of 28 percent year-on-year. The increase for disposables was very strong at 39 percent, or 32 percent adjusted for currency effects. Total growth, adjusted for currency effects, totaled 22 percent.

The gross margin for disposables increased to 53 percent (51), primarily driven by price increases in liver transplant products.

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, 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 10-15 US thoracic clinics with their services. The company was acquired on November 9, 2021, which is why there are no comparative figures in the Group's accounts.

Summary

SEK Thousands	January-September 2022	January-September 2021	July-September 2022	July-September 2021
Net sales	32 080	-	11 926	-
Gross margin, %	50	-	45	-

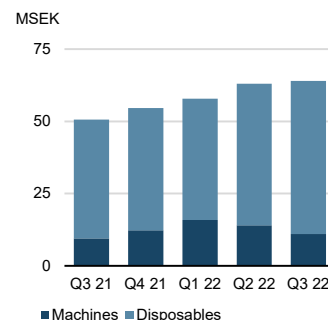
The quarter July - September 2022

STAR Teams' sales experienced organic growth of 23 percent year-on-year, primarily driven by an increased customer base of thoracic clinics. The number of organ recoveries increased by 24 percent year-on-year. The gross margin was 45 percent and is expected to increase as the customer base expands and economies of scale are generated.

The period January - September 2022

STAR Teams increased the number of organ recoveries by 32 percent year-on-year and sales growth amounted to 37 percent.

Net sales Abdominal (R12)



Net sales per product category, Abdominal (Q3)







Organ recoveries in Q3


+23%

R&D Portfolio

Development projects

Project	Description	Status
Heart transplantation 	<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, twelve clinics now actively include patients in XVIVO's study. Four more clinics are in the start-up phase. All of the clinics have made preparations and been given training. 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 reported successful transplants using donated hearts that had been transported for more than 8 hours using XVIVO's technology. An additional number of pre-clinical initiatives are underway or have been started by leading researchers within heart transplantation.</p>
Kidney transplantation 	<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 the kidney technology into a more mature phase. The combination of new perfusion technology and solutions will be the focus of future research in the field of organs.</p>
Liver transplantation 	<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 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>
PrimECC® 	<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. Planning is underway to add additional centers in Germany and Norway.</p>

Research projects

Project	Description	Status
Xenotransplantation 	<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 two 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

XVIVO employs 118 people, of whom 55 are women and 63 men. Of these, 46 are employed in Sweden and 72 outside Sweden. The head office is located in Gothenburg, Sweden and our subsidiaries are located in Lund, Sweden, Denver and Philadelphia, the US and Groningen, the Netherlands. XVIVO also has employees based in several other countries in Europe, China, Australia and Brazil.

Related-party transactions

During 2022, the 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.

Outlook

The geopolitical situation remains tense. XVIVO currently has very limited sales exposure to Eastern Europe and the procurement chain is not exposed to these markets. All XVIVO’s manufacturing takes place either in Western Europe or the US. Accordingly, we currently 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 2022 and 2023 remains largely dependent on how much the intensive care operations in our main markets in the US and Europe are affected. As fewer healthcare resources are targeted at Covid patients, the company expects resources to be freed up to increase the number of transplantations through machine perfusion.

We see continued growing interest in our perfusion technologies across all organ areas. The primary commercial focus is still to broaden the installed base of perfusion machines and to increase their use. A great emphasis will be placed on increasing the production rate of Kidney Assist Transport machines to support the ongoing launch in 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 is expected to include its final patient in as early as the fourth quarter. 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.

Significant events after the end of the period

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

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

Gothenburg, October 27, 2022

Christoffer Rosenblad
Acting 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 Thursday, October 27, 2022 at 7.30 am CEST.



Financial calendar

- Year-End Report 2022:
Thursday, January 26, 2023
- Interim Report January-March 2023:
Monday, April 24, 2023
- Interim Report January-June 2023:
Thursday, July 13, 2023
- Interim Report January-September 2023: Tuesday, October 24, 2023



Conference call

Acting 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 27, 2022.
Telephone SWE: +46 (0)8 566 426 51
Telephone UK: +44 3333 000804
Telephone US: +1 6319 131422
PIN: 82398789#



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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 2022 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 Review of Interim Financial Information Performed by the Independent Auditor of the Entity. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Gothenburg 27th October 2022

KPMG AB

Daniel Haglund

Authorized Public Accountant

Financial statements

Condensed Consolidated Statement of Net Income

SEK Thousands	January-September 2022	January-September 2021	July-September 2022	July-September 2021	January-December 2021
Net sales	283 778	172 523	96 835	54 935	258 386
Cost of goods sold	-81 679	-47 234	-27 464	-16 977	-70 107
Gross income	202 099	125 289	69 371	37 958	188 279
Selling expenses	-106 680	-62 242	-39 387	-23 530	-97 216
Administrative expenses	-47 913	-34 592	-18 734	-9 049	-55 687
Research and development expenses	-45 384	-38 563	-16 651	-10 428	-54 039
Other operating revenues and expenses	1 983	-90	744	1 018	165
Operating income	4 105	-10 198	-4 657	-4 031	-18 498
Financial income and expenses	15 458	6 626	7 649	2 956	25 163
Income after financial items	19 563	-3 572	2 992	-1 075	6 665
Taxes	-1 870	-465	2 406	-54	1 487
Net income	17 693	-4 037	5 398	-1 129	8 152
Attributable to					
Parent Company's shareholders	17 693	-4 037	5 398	-1 129	8 152
Earnings per share, SEK	0,60	-0,14	0,18	-0,04	0,28
Earnings per share, SEK ¹⁾	0,60	-0,14	0,18	-0,04	0,28
Average number of outstanding shares	29 505 699	28 723 201	29 512 733	28 727 266	28 845 691
Average number of outstanding shares ¹⁾	29 505 699	28 847 868	29 512 733	29 101 266	28 936 075
Number of shares at closing day	29 561 967	28 752 397	29 561 967	28 752 397	29 498 666
Number of shares at closing day ¹⁾	29 561 967	29 126 397	29 561 967	29 126 397	29 872 666
EBITDA (Operating income before depreciation and amortization)	34 996	13 855	5 904	4 181	13 759
Depreciation and amortization on intangible assets	-20 726	-15 883	-6 891	-5 278	-21 219
Depreciation and amortization on tangible assets	-10 165	-8 170	-3 670	-2 934	-11 038
Operating income	4 105	-10 198	-4 657	-4 031	-18 498

¹⁾ After dilution

Consolidated Statement of Total Comprehensive Income

SEK Thousands	January-September 2022	January-September 2021	July-September 2022	July-September 2021	January-December 2021
Net income	17 693	-4 037	5 398	-1 129	8 152
Other comprehensive income					
Items that may be reclassified to the income statement					
Exchange rate differences	77 866	6 877	30 381	3 163	22 271
Total other comprehensive income	77 866	6 877	30 381	3 163	22 271
Total comprehensive income	95 559	2 840	35 779	2 034	30 423
Attributable to					
Parent Company's shareholders	95 559	2 840	35 779	2 034	30 423

Condensed Consolidated Statement of Financial Position

SEK Thousands	220930	210930	211231
ASSETS			
Goodwill	525 648	226 801	460 228
Capitalized development expenditure	523 498	432 845	456 551
Other intangible fixed assets	8 547	8 696	8 658
Fixed assets	36 978	21 706	26 297
Financial assets	40 853	41 440	43 330
Total non-current assets	1 135 524	731 488	995 064
Inventories	89 996	78 999	77 590
Current receivables	101 418	49 374	71 246
Liquid funds	314 561	284 516	398 696
Total current assets	505 975	412 889	547 532
Total assets	1 641 499	1 144 377	1 542 596
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity, attributable to the Parent Company's shareholders	1 381 633	1 012 541	1 285 450
Long-term interest-bearing liabilities	1 387	746	1 522
Long-term non-interest-bearing liabilities	172 110	68 478	151 105
Short-term interest-bearing liabilities	4 158	3 925	4 199
Short-term non-interest-bearing liabilities	82 211	58 687	100 320
Total shareholders' equity and liabilities	1 641 499	1 144 377	1 542 596

Condensed Consolidated Cash Flow Statements

	January- September 2022	January- September 2021	July-September 2022	July-September 2021	January- December 2021
Income after financial items	19 563	-3 572	2 992	-1 075	6 665
Adjustment for items not affecting cash flow	13 301	12 282	2 785	3 324	7 195
Paid taxes	-1 592	-2 205	-556	-462	-2 701
Change in inventories	4 209	-12 906	-6 304	-3 454	-13 802
Change in trade receivables	-19 213	4 531	11 052	-194	-8 294
Change in trade payables	-10 201	-9 627	7 002	-6 594	-1 122
Cash flow from operating activities	6 067	-11 497	16 971	-8 455	-12 059
Cash flow from investing activities	-120 570	-62 545	-33 723	-20 207	-187 703
Cash flow from financing activities	-4 042	-2 284	-1 621	-1 357	234 611
Cash flow for the period	-118 545	-76 326	-18 373	-30 019	34 849
Liquid funds at beginning of period	398 696	354 236	317 885	311 419	354 236
Exchange rate difference in liquid funds	34 410	6 606	15 049	3 116	9 611
Liquid funds at end of period	314 561	284 516	314 561	284 516	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 - September 2021	-	-	6 877	-4 037	2 840
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	1	-	-	-	1
Share warrant program	-	1 239	-	-	1 239
Shareholders' equity as of September 30, 2021	735	1 008 023	6 694	-2 911	1 012 541
Total comprehensive income October - December 2021	-	-	15 394	12 189	27 583
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	19	245 307	-	-	245 326
Share warrant program	-	-	-	-	-
Shareholders' equity as of December 31, 2021	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 after 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

Condensed Consolidated Statement of Net Income per quarter

SEK Thousands	Jul-Sep 2022	Apr-Jun 2022	Jan-Mar 2022	Oct-Dec 2021	Jul-Sep 2021	Apr-Jun 2021	Jan-Mar 2021	Oct-Dec 2020
Net sales	96 835	94 289	92 654	85 863	54 935	59 263	58 325	60 277
Cost of goods sold	-27 464	-26 783	-27 432	-22 873	-16 977	-15 009	-15 248	-19 466
Gross income	69 371	67 506	65 222	62 990	37 958	44 254	43 077	40 811
Selling expenses	-39 387	-37 774	-29 519	-34 974	-23 530	-22 975	-15 737	-23 878
Administrative expenses	-18 734	-14 779	-14 400	-21 095	-9 049	-14 856	-10 687	-11 056
Research and development costs	-16 651	-12 075	-16 658	-15 476	-10 428	-14 988	-13 147	-18 891
Other operating revenues and expenses	744	1 260	-21	255	1 018	-785	-323	-1 314
Operating income	-4 657	4 138	4 624	-8 300	-4 031	-9 350	3 183	-14 328
Financial income and expenses	7 649	6 244	1 565	18 537	2 956	-1 411	5 081	-11 610
Income after financial items	2 992	10 382	6 189	10 237	-1 075	-10 761	8 264	-25 938
Taxes	2 406	-2 852	-1 424	1 952	-54	1 820	-2 231	6 363
Net income	5 398	7 530	4 765	12 189	-1 129	-8 941	6 033	-19 575
Attributable to								
Parent Company's shareholders	5 398	7 530	4 765	12 189	-1 129	-8 941	6 033	-19 575
Earnings per share, SEK	0,18	0,26	0,16	0,42	-0,04	-0,31	0,21	-0,68
Earnings per share, SEK ¹⁾	0,18	0,26	0,16	0,41	-0,04	-0,31	0,20	-0,67
Average number of outstanding shares	29 512 733	29 512 733	29 498 666	29 241 732	28 727 266	28 727 266	28 719 136	28 719 136
Average number of outstanding shares ¹⁾	29 512 733	29 512 733	29 872 666	29 615 732	29 101 266	29 101 266	29 444 136	29 327 136
Number of shares at closing day	29 561 967	29 561 967	29 498 666	29 498 666	28 752 397	28 752 397	28 719 136	28 719 136
Number of shares at closing day ¹⁾	29 561 967	29 561 967	29 872 666	29 872 666	29 126 397	29 126 397	29 444 136	29 444 136
EBITDA (Operating income before depreciation and amortization)	5 904	14 399	14 693	-96	4 181	-1 533	11 207	-6 506
Depreciation and amortization on intangible assets	-6 891	-6 929	-6 906	-5 336	-5 278	-5 135	-5 470	-5 349
Depreciation and amortization on tangible assets	-3 670	-3 332	-3 163	-2 868	-2 934	-2 682	-2 554	-2 473
Operating income	-4 657	4 138	4 624	-8 300	-4 031	-9 350	3 183	-14 328

¹⁾ After dilution

Consolidated Statement of Total Comprehensive Income per quarter

SEK Thousands	Jul-Sep 2022	Apr-Jun 2022	Jan-Mar 2022	Oct-Dec 2021	Jul-Sep 2021	Apr-Jun 2021	Jan-Mar 2021	Oct-Dec 2020
Net income	2	7 530	4 765	12 189	-1 129	-8 941	6 033	-19 575
Other comprehensive income								
Items that may be reclassified to the income statement:								
Exchange rate differences	30 381	37 862	9 623	15 394	3 163	-3 704	7 418	-13 179
Tax attributable to items that have been transferred, or can be transferred to net income	-	-	-	-	-	-	-	-153
Total other comprehensive income	30 381	37 862	9 623	15 394	3 163	-3 704	7 418	-13 332
Total comprehensive income	35 779	45 392	14 388	27 583	2 034	-12 645	13 451	-32 907
Attributable to								
Parent Company's shareholders	35 779	45 392	14 388	27 583	2 034	-12 645	13 451	-32 907

Consolidated Key Ratios

SEK Thousands	January-September 2022	January-September 2021	July-September 2022	July-September 2021	January-December 2021
Gross margin, %	71	73	72	69	73
Gross margin disposables, %	79	75	79	73	76
EBIT, %	1	-6	-5	-7	-7
EBIT (adjusted), %	2	-2	-1	-5	-1
EBITDA, %	12	8	6	8	5
EBITDA (adjusted), %	13	12	10	10	11
Net margin, %	6	-2	6	-2	3
Equity/assets ratio, %	84	88	84	88	83
Income per share, SEK	0,60	-0,14	0,18	-0,04	0,28
Shareholders' equity per share, SEK	46,74	35,22	46,74	35,22	43,58
Share price on closing day, SEK	134	387	134	387	279
Market cap on closing day, MSEK	3 961	11 113	3 961	11 113	8 230

Condensed Income Statement for the Parent Company

SEK Thousands	January-September 2022	January-September 2021	July-September 2022	July-September 2021	January-December 2021
Net sales	172 870	124 347	58 009	28 352	161 287
Cost of goods sold	-37 202	-24 498	-13 736	-6 246	-30 757
Gross income	135 668	99 849	44 273	22 106	130 530
Selling expenses	-45 410	-33 254	-15 248	-13 775	-52 486
Administrative expenses	-39 806	-30 692	-11 907	-4 392	-39 907
Research and development expenses	-37 334	-33 871	-12 531	-9 923	-45 372
Other operating revenues and expenses	1 900	-390	574	1 662	-125
Operating income	15 018	1 642	5 161	-4 322	-7 360
Financial income and expenses	17 963	7 820	8 651	3 467	6 475
Income after financial items	32 981	9 462	13 812	-855	-885
Taxes	-7 004	-2 975	-2 849	88	-181
Net income	25 977	6 487	10 963	-767	-1 066

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 14,404 (14,583) thousands, of which SEK 4,815 (4,820) thousands in the quarter.

Condensed Balance Sheet for the Parent Company

SEK Thousands	220930	210930	211231
ASSETS			
Intangible fixed assets	346 418	274 536	292 229
Property, plant and equipment	10 677	6 264	8 980
Financial assets	792 380	501 742	719 916
Total non-current assets	1 149 475	782 542	1 021 125
Inventories	17 696	19 074	21 805
Current receivables	34 739	20 739	25 258
Cash and bank	274 130	260 179	369 479
Total current assets	326 565	299 992	416 542
Total assets	1 476 040	1 082 534	1 437 667
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	1 272 871	1 008 544	1 246 317
Provisions	1 328	1 454	1 499
Long-term non-interest-bearing liabilities	146 138	41 973	124 522
Short-term non-interest-bearing liabilities	55 703	30 563	65 329
Total shareholders' equity and liabilities	1 476 040	1 082 534	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 cost amounted to SEK 416 million (354) and SEK 72 million (63) 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 160.2 million (42.0) relating to additional purchase consideration linked to acquisitions. Additional purchase consideration is 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 30.5 million (1.8) 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	220930	210930	211231
Opening balance	150 676	40 150	40 150
Additional purchase considerations	-	-	129 650
Reversal of additional purchase considerations	-	-	-20 454
Payment of additional purchase considerations	-20 976	-	-
Exchange-rate differences	30 459	1 823	1 330
Closing balance	160 159	41 973	150 676

Note 3. Net sales

Distribution of net sales

SEK Thousands	January-September							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
Disposables	191 836	132 748	37 954	27 265	-	-	229 790	160 013
Machines	16 352	5 810	5 556	6 700	-	-	21 908	12 510
Services	-	-	-	-	32 080	-	32 080	-
Nettoomsättning	208 188	138 558	43 510	33 965	32 080	-	283 778	172 523

SEK Thousands	July-September							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
Disposables	69 188	39 940	12 640	8 953	-	-	81 828	48 893
Machines	2 038	2 330	1 043	3 712	-	-	3 081	6 042
Services	-	-	-	-	11 926	-	11 926	-
Nettoomsättning	71 226	42 270	13 683	12 665	11 926	-	96 835	54 935

Net sales by geographical area

SEK Thousands	January-September							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
North America	132 404	87 096	6 439	1 831	32 080	-	170 923	88 928
South and Latin America	4 271	1 817	-	1 032	-	-	4 271	2 849
EMEA	61 125	40 509	34 695	29 913	-	-	95 820	70 421
Asia and Pacific	10 389	9 136	2 375	1 189	-	-	12 764	10 325
Nettoomsättning	208 188	138 558	43 510	33 965	32 080	-	283 778	172 523

SEK Thousands	July-September							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
North America	50 630	25 009	927	-1	11 926	-	63 483	25 009
South and Latin America	1 604	1 073	-	0	-	-	1 604	1 073
EMEA	16 109	13 012	12 661	11 756	-	-	28 770	24 767
Asia and Pacific	2 884	3 176	94	910	-	-	2 978	4 086
Nettoomsättning	71 226	42 270	13 683	12 665	11 926	-	96 835	54 935

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-September							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
Net sales	208 188	138 558	43 510	33 965	32 080	-	283 778	172 523
Cost of goods sold	-45 075	-30 616	-20 507	-16 618	-16 097	-	-81 679	-47 234
Gross income	163 113	107 942	23 003	17 347	15 983	-	202 099	125 289
Gross margin (%)	78	78	53	51	50	-	71	73

SEK Thousands	July-September							
	Thoracic		Abdominal		Services		Total consolidated	
	2022	2021	2022	2021	2022	2021	2022	2021
Net sales	71 226	42 270	13 683	12 665	11 926	-	96 835	54 935
Cost of goods sold	-13 698	-10 619	-7 167	-6 358	-6 599	-	-27 464	-16 977
Gross income	57 528	31 651	6 516	6 307	5 327	-	69 371	37 958
Gross margin (%)	81	75	48	50	45	-	72	69

Note 5. Business acquisitions

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 consideration of up to USD 26.1 million with an initial payment of USD 12.3 million and a potential additional purchase consideration of up to USD 13.8 million. The additional purchase consideration 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 consideration is instead based on a combination of revenue and gross margin targets in 2024.

Costs attributable to the acquisition totaled SEK 10.0 million and were recognized as Administrative expenses in the Group Income Statement in 2021. In 2021, STAR Teams contributed SEK 6.1 million to Group revenue and SEK 1.5 million to Group profit.

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 has 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 in 2023. 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 as of September 30, 2022 is still preliminary and will be completed during the fall. The table below presents the initial, preliminary acquisition analysis*.

Acquisition of business

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

* 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 2022.

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

SEK Thousands	January-September 2022	January-September 2021	July-September 2022	July-September 2021	January-December 2021
Operating income	4 105	-10 198	-4 657	-4 031	-18 498
Depreciation and amortization on intangible assets	20 726	15 883	6 891	5 278	21 219
Depreciation and amortization on tangible assets	10 165	8 170	3 670	2 934	11 038
EBITDA (Operating income before depreciation and amortization)	34 996	13 855	5 904	4 181	13 759

EBITDA (adjusted)

SEK Thousands	January-September 2022	January-September 2021	July-September 2022	July-September 2021	January-December 2021
EBITDA (Operating income before depreciation and amortization)	34 996	13 855	5 904	4 181	13 759
Acquisition costs	3 963	3 394	3 963	1	13 350
Integration costs	3 955	5 821	195	994	6 334
Cash-based incentive programs for employees outside Europe	-6 279	-3 094	-154	130	-3 902
EBITDA (adjusted)	36 635	19 976	9 908	5 306	29 541

EBIT (adjusted)

SEK Thousands	January-September 2022	January-September 2021	July-September 2022	July-September 2021	January-December 2021
EBIT (Operating income)	4 105	-10 198	-4 657	-4 031	-18 498
Acquisition costs	3 963	3 394	3 963	1	13 350
Integration costs	3 955	5 821	195	994	6 334
Cash-based incentive programs for employees outside Europe	-6 279	-3 094	-154	130	-3 902
EBIT (adjusted)	5 744	-4 077	-653	-2 906	-2 716

Gross profit margin

SEK Thousands	January-September 2022	January-September 2021	July-September 2022	July-September 2021	January-December 2021
Operating income					
<i>Net sales</i>	283 778	172 523	96 835	54 935	258 386
Operating expenses					
<i>Cost of goods sold</i>	-81 679	-47 234	-27 464	-16 977	-70 107
Gross income	202 099	125 289	69 371	37 958	188 279
Gross margin %	71	73	72	69	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

SEK Thousands	220930	210930	211231
Shareholders' equity	1 381 633	1 012 541	1 285 450
Total assets	1 641 499	1 144 377	1 542 596
Equity/assets ratio %	84	88	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, acquisitions and divestments. Acquisitions and divestments are adjusted for by excluding net sales during the entire period for any acquisitions or divestments made in the previous year or current year that were not consolidated for the entire period the previous year. Currency effects are calculated by recalculating the period's and previous period's sales in local currencies 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.



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