



Interim report January – March 2023

XVIVO Perfusion AB (publ)

XVIVO

First quarter 2023 (Jan 1 – Mar 31)

- Net sales amounted to SEK 140.6 million (92.7), corresponding to an increase of 52 percent in SEK and 39 percent adjusted for currency effects. Organic growth accounted for 34 percent and acquired growth for 5 percent.
- All business areas delivered underlying growth adjusted for currency effects: Thoracic 23 percent, Abdominal 85 percent and Services 81 percent.
- The gross margin for disposables increased to 81 percent (79). The total gross margin rose to 75 percent (70).
- Operating income (EBIT) amounted to SEK 11.2 million (4.6). Adjusted EBIT amounted to SEK 12.5 million (5.3).
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 23.6 million (14.7) corresponding to an EBITDA margin of 17 percent (16). Adjusted operating income before depreciation and amortization (EBITDA) amounted to SEK 24.9 million (15.4), corresponding to an adjusted EBITDA margin of 18 percent (17).
- Net income amounted to SEK 14.2 million (4.8). Earnings per share amounted to SEK 0.48 (0.16).
- Cash flow from operating activities was SEK -12.4 million (-9.3), primarily due to the payment of personnel-related operating liabilities earned in 2022. Total cash flow amounted to SEK -48.4 million (-63.6), impacted by investments in R&D projects of SEK -22.6 million.

Significant events during the quarter

- Successful integration of Avionord M&P.
- In a pre-clinical study published in The Journal of Heart and Lung Transplantation, benefits of XVIVO's heart preservation technology have now been demonstrated also in donation after circulatory death (DCD).
- Great interest in Australia and New Zealand for XVIVO's heart technology. Approximately 25 percent of the countries' heart transplants were performed using our technology during the quarter.
- Strengthened proof of the benefits of cold oxygenized perfusion of liver in donation after brain death (DBD) demonstrated in large multicenter study published in Journal of Hepatology.

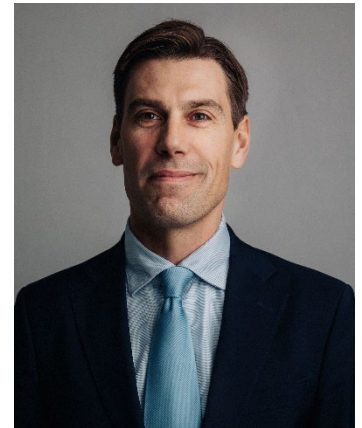
Key ratios

	January-March 2023	January-March 2022	Full year 2022
TSEK			
Net sales	140 615	92 654	415 292
Gross margin, %	75	70	72
Gross margin disposables, %	81	79	79
EBIT	11 207	4 624	6 409
EBIT (adjusted) ¹⁾	12 451	5 311	14 285
EBITDA	23 644	14 693	48 576
EBITDA (adjusted) ¹⁾	24 888	15 380	56 452
Cash flow from operating activities	-12 427	-9 347	27 856
Earnings per share, SEK	0,48	0,16	0,62
Changes in net sales			
Organic growth in local currency, %	34	32	30
Acquired growth, %	5	15	15
Currency effect, %	13	12	16
Total growth, %	52	59	61

¹⁾Adjusted for effect from integration costs. Net adjustment totals SEK -1.3 (-0.7) million for the quarter.

Record quarter for sales and gross margin

XVIVO's strong sales growth continued in the first quarter of the year. Total sales amounted to SEK 141 million, with all business areas showing continued growth. An increase in gross margin, particularly in Abdominal, contributed to an adjusted EBITDA margin of 18 percent. In addition to our operational success, we were pleased to note that our technologies for machine perfusion of both heart and liver were again highlighted in convincing scientific articles during the quarter.



Christoffer Rosenblad, CEO

Total sales in the quarter amounted to SEK 141 million (93), equivalent to growth of 52 percent. Organic growth accounted for 34 percent and acquired growth amounted to 5 percent. The remaining growth related to currency effects.

Sales in the **Thoracic** business area amounted to SEK 91 million (68), an increase of 33 percent year-on-year and an increase of 23 percent adjusted for currency effects. Disposables delivered organic growth of 32 percent. It is especially pleasing that we have begun generating sales of our heart preservation technology in Australia and New Zealand. The clinics in the now completed investigator-initiated trial have continued to use our technology via special permits. An estimated 25 percent of these countries' heart transplants were performed using our technology during the quarter. Several of these transplants would previously have been impossible to perform.

Abdominal delivered yet another strong quarter, thanks to continued positive sales growth for liver perfusion in Europe. Sales amounted to SEK 31 million (15) in the quarter, equivalent to growth of 85 percent adjusted for currency effects. Disposables delivered organic growth of 82 percent. The business area showed strong margin improvements, driven by a general positive price development as well as the now integrated business model used in Italy, in which our own perfusionists take care of the actual perfusion process. Gross margin amounted to 65 percent (55). Kidney Assist Transport has started to be delivered and installed for customers in the US and Europe.

The **Services** business area, which consists of our organ recovery service in the US, had organic growth of 82 percent. The trend in the US is clear - more and more transplant clinics are recognizing the benefits of outsourcing all or parts of their organ recovery process to external, specialized operators such as XVIVO. We are now focusing strongly on strengthening our surgical capacity and our logistics network in order to optimize time and costs for clinics.

The EBITDA margin for the quarter, adjusted for integration costs, was 18 percent (17), which is an improvement of 15 percent compared to the previous quarter. During the quarter, we worked intensively with preparations for the spring industry conferences, including the annual international meeting ISHLT in Denver, USA, in April.

On the clinical front, our technologies continue to generate compelling clinical data, something we are extremely proud of. In a pre-clinical study, a research team showed that cold oxygenated perfusion of donor hearts using XVIVO's heart preservation technology has potential to be used successfully in DCD donation. Another published study highlights strong evidence of the benefits of cold oxygenated perfusion of livers from DBD donors. Both studies indicate a broad future potential for our technologies. More about these studies on page 7.

In summing up the first quarter, it can be concluded that our dedicated, focused efforts in recent years are paying off in the form of strong growth, good margins and the achievement of significant milestones in heart and liver. To continue this journey, the company will focus even more clearly on developing its current business, continue the launch of Kidney Assist Transport in the US and Europe, and obtain regulatory approval for our heart technology in the EU, Australia and the US as well as receiving a regulatory FDA approval for our liver technology in the US. We will strengthen our focus on enabling more patients' lives to be saved and on one day achieving our vision that nobody should die waiting for a new organ.

Christoffer Rosenblad, CEO

“Our dedicated, focused efforts in recent years are paying off in the form of strong growth and good margins”

This is XVIVO

Founded in 1998, XVIVO is the only MedTech company dedicated to extending the life of all major organs – so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of organ transplantation. XVIVO is a global company headquartered in Gothenburg, Sweden. The company is listed on Nasdaq.

Business concept and goals

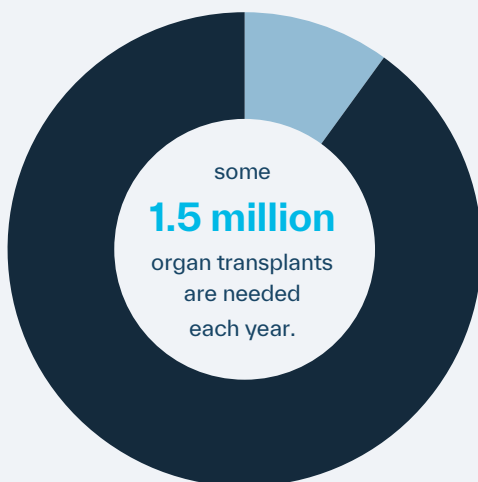
XVIVO's business concept is to develop and market effective, innovative technology for preserving, transporting and assessing organs outside the body while awaiting transplant, and to facilitate the transplant process by offering services in the form of organ recovery and organ perfusion.

Our goals

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

Purpose and vision

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



With only

150,000

organ transplants
each year, only

10%

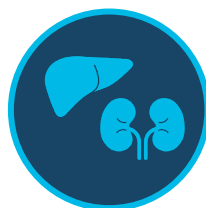
of total global demand
is met

XVIVO's offer increases the
availability of transplantable
organs

Our business areas



Thoracic



Abdominal



Services

Compilation of net sales and EBITDA

SEK Thousands	January-March 2023	January-March 2022	Full year 2022
Net Sales Thoracic	90 914	68 101	296 353
Net Sales Abdominal	30 550	15 066	70 861
Net Sales Services	19 151	9 487	48 078
Net Sales Total	140 615	92 654	415 292
Gross profit Thoracic	75 883	52 159	235 676
Gross margin Thoracic, %	83%	77%	80%
Gross profit Abdominal	19 743	8 298	37 733
Gross margin Abdominal, %	65%	55%	53%
Gross profit Services	9 191	4 765	23 547
Gross margin Services, %	48%	50%	49%
Gross profit Total	104 817	65 222	296 956
Gross margin Total, %	75%	70%	72%
Selling expenses	-48 375	-29 519	-152 398
Administrative expenses	-18 985	-14 400	-70 979
Research and development expenses	-26 173	-16 658	-69 343
Other operating income and expenses	-77	-21	2 173
Operating Income	11 207	4 624	6 409
Amortization and depreciation cost of goods sold	108	185	744
Amortization and depreciation administrative expenses	971	877	3 402
Amortization and depreciation research and development expenses	8 656	7 609	31 024
Amortization and depreciation selling expenses	2 702	1 398	6 997
EBITDA (Operating income before depreciation and amortization)	23 644	14 693	48 576
EBITDA, %	17%	16%	12%
EBITDA (adjusted) ²⁾	24 888	15 380	56 452
EBITDA (adjusted), %	18%	17%	14%

¹⁾ Adjusted for effect from integration costs. Net adjustment totals SEK -1.3 (-0.7) million for the quarter.

Summary

January-March 2023

Net sales and income

Net sales in the quarter amounted to SEK 140.6 million (92.7), equivalent to growth of 52 percent year-on-year. The organic growth was 34 percent, acquired growth was 5 percent and the remaining 13 percent constituted currency effects. All business areas demonstrated solid growth. For a description of development within each business area, see pages 8-9.

The total gross margin for the quarter was 75 percent (70). During the quarter, the gross margin for disposables increased year-on-year both for Thoracic and Abdominal, with a margin of 86 percent (84) for Thoracic and 65 percent (53) for Abdominal. For comments regarding the margins in each business area, see pages 8-9.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 23.6 million (14.7), corresponding to an EBITDA margin of 17 percent (16). EBITDA was affected by integration costs of SEK -1.3 million. Adjusting for these items, EBITDA amounted to SEK 24.9 million (15.4), corresponding to an adjusted EBITDA margin of 18 percent (17).

Operating income (EBIT) amounted to SEK 11.2 million (4.6). EBIT adjusted for the aforementioned costs amounted to SEK 12.5 million (5.3).

Selling expenses in relation to sales amounted to 34 percent (32) for the quarter. R&D expenses amounted to 19 percent (18) of sales. Administrative expenses amounted to 14 percent (16).

Capitalization and amortization

During the quarter, SEK 22.6 million (27.0) 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 7.2 million (6.6) in the quarter.

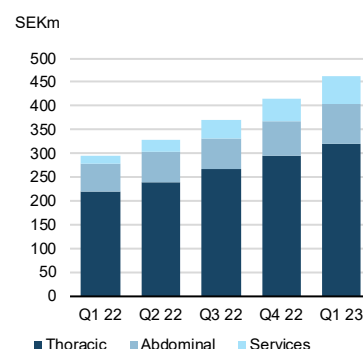
Cash flow

Cash flow from operating activities was SEK -12.4 million (-9.3) in the quarter, primarily due to payment of personnel-related operating liabilities attributable to 2022. Cash flow from investing activities amounted to SEK -33.5 million (-52.4), of which SEK -23.2 million (-27.5) was invested in intangible assets and SEK -10.3 million (-3.9) was invested in tangible assets. Cash flow from financing activities amounted to net SEK -2.5 million (-1.9). Exchange rate differences impacted the cash flow for the quarter by SEK -0.2 million (4.7). Cash and cash equivalents at the end of the quarter amounted to SEK 198.0 million (339.8).

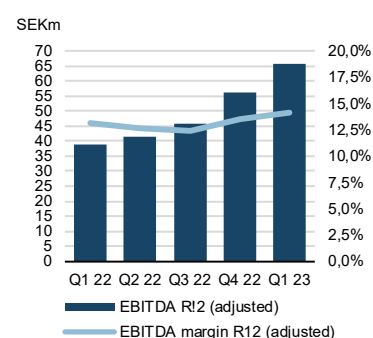
Financing

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 by business area (R12)



EBITDA and EBITDA margin (adjusted, R12)



Significant events during the quarter

Successful integration of Avionord M&P

The integration of our Italian distributor was completed as planned during the quarter. Avionord M&P was acquired at the end of last year and the business now operates under the name XVIVO S.r.l. The concept of offering XVIVO's organ perfusion machines in combination with a perfusionist who handles the perfusion process contributed to a significantly improved gross margin for the Abdominal business area during the quarter.

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

The last patient in the investigator-initiated heart preservation study in Australia and New Zealand received a transplant towards the end of 2022. Pending regulatory approval for these geographies, which is dependent on CE marking under MDR, special permits have been granted that allow hearts to be treated with products that have not received regulatory approval. There is very strong interest in continuing to use XVIVO's technology. Four out of five trial centers purchased and used our products during the first quarter, and the fifth center is expected to soon follow suit. Approximately 25 percent of the countries' heart transplants during the first quarter were performed using XVIVO's technology.

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

The Journal of Heart and Lung Transplantation recently published an article¹ from a research team led by professor H Eiskjaer, Aarhus, Denmark. In a large animal model, the team successfully showed the potential for using XVIVO's heart preservation technology for hearts from DCD² donors. The study shows that DCD hearts can successfully be transplanted both after direct procurement and after normothermic regional perfusion (NRP) of the donor organ if XVIVO's technology is used.

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

XVIVO's liver perfusion technology, Liver Assist, offers hypothermic oxygenated perfusion (HOPE) for the liver. The advantages of the technology over traditional static cold storage for DCD livers were highlighted in the New England Journal of Medicine in 2021. During the quarter, the Journal of Hepatology³ published the results of a randomized multicenter trial showing positive effects if HOPE is also used for livers from DBD⁴ donors. Today the majority of donated livers are DBD livers.

¹ [https://www.jhltonline.org/article/S1053-2498\(25\)00035-5/fulltext](https://www.jhltonline.org/article/S1053-2498(25)00035-5/fulltext)

² DCD: Donation after circulatory death

³ [https://www.journal-of-hepatology.eu/article/S0168-8278\(25\)00012-0/fulltext#%20](https://www.journal-of-hepatology.eu/article/S0168-8278(25)00012-0/fulltext#%20)

⁴ DBD: Donation after brain death

Business area development

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

Thoracic

The Thoracic business area comprises XVIVO's products for lung and heart transplantation. In lung transplantation, the company's product Perfadex® Plus has a market share of approximately 90 percent in traditional static preservation of lungs. The company's products for warm perfusion, XPS™ and STEEN Solution™, have regulatory approval in all major markets and in 2019 they were the first products to receive FDA clearance for warm perfusion of marginal lungs. In heart transplantation, XVIVO's products are in a clinical study phase. Sales in clinical heart transplantation have begun in 2023 in Australia and New Zealand, and since a couple of years back, pre-clinical sales have been conducted to support research in xenotransplantation.

Summary

SEK Thousands	January-March 2023	January-March 2022	Full year 2022
Net sales	90 914	68 101	296 353
Disposables	85 593	59 418	276 589
Machines	5 321	8 683	19 764
Gross margin, %	83	77	80
Disposables	86	84	84
Machines	41	25	15

January-March 2023

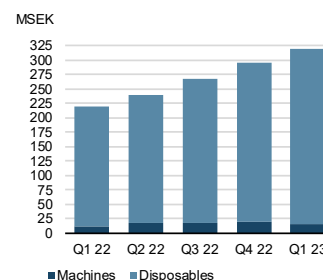
Thoracic delivered a strong first quarter. Sales amounted to SEK 90.9 million (68.1), equivalent to growth of 33 percent year-on-year or 23 percent adjusted for currency effects.

The momentum we experienced in EVLP in 2022 continued during the first quarter. Machine perfusion accounted for 50 percent (47) of net sales. Static preservation and other sales accounted for the remainder of net sales.

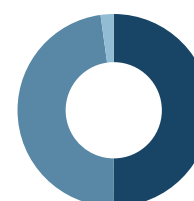
Sales of disposables delivered organic growth of 32 percent.

The gross margin for disposables increased to 86 percent (84). The improved margin compared to the previous quarter is primarily due to the positive price development and favorable currency effects.

Net sales Thoracic (R12)



Net sales by product category Thoracic (Q1)



Abdominal

The Abdominal business area comprises XVIVO's product and service operations in liver and kidney transplantation. XVIVO offers oxygenated machine perfusion products for both these organs. Products for liver and kidney transplants are primarily sold in selected markets in Europe, but also in other smaller markets. In 2023 we will accelerate the introduction of the company's kidney preservation product, Kidney Assist Transport, in all major markets.

Summary

SEK Thousands	January-March 2023	January-March 2022	Full year 2022
Net sales	30 550	15 066	70 861
Disposables	26 039	10 762	59 877
Machines	4 511	4 304	10 984
Gross margin, %	65	55	53
Disposables	65	53	54
Machines	64	61	51

January-March 2023

Sales amounted to SEK 30.6 million (15.1) in the quarter, representing an increase of 103 percent year-on-year. Adjusted for currency effects, growth totaled 85 percent. The increase for disposables was strong at 142 percent, or 123 percent adjusted for currency effects, of which organic growth accounted for 82 percent and acquired growth for 41 percent. The revenue was primarily generated in Europe, and approximately 78 percent related to liver perfusion.

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

Services

The Services business area comprises STAR Teams' organ recovery operations in the US in the area of thoracic. Organ recovery means the removal of organs from the donor body, the preservation of organs in cold fluid during transport, and logistics and coordination ahead of and during organ recovery. STAR Teams provide around 15 US thoracic clinics with their services.

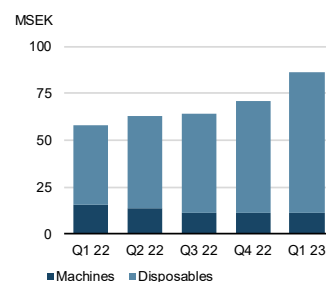
Summary

SEK Thousands	January-March 2023	January-March 2022	Full year 2022
Net sales	19 151	9 487	48 078
Gross margin, %	48	50	49

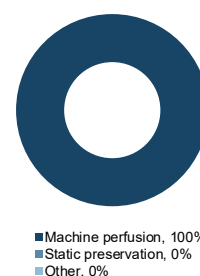
January-March 2023

STAR Teams' sales experienced organic growth of 82 percent year-on-year, primarily driven by an increased customer base. The number of organ retrievals increased by 24 percent compared to last year's quarter. The demand for organ recovery services from US clinics continues to grow. A number of recruitment processes were started during the quarter with the aim of broadening the organization to meet growing demand. The gross margin was 48 percent and is expected to increase as the customer base expands and economies of scale are generated.

Net sales Abdominal (R12)



Net sales by product category, Abdominal (Q1)







Organ recoveries in Q1


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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 time a donated heart can survive outside the body. In collaboration with Professor Stig Steen, XVIVO has developed a comprehensive solution comprising fluids and machinery that 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 transplant 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 the application for regulatory approval for the products in all major markets worldwide. In Europe, all fifteen clinics have recruited patients in XVIVO's study. The initial experiences reported by 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.</p> <p>An additional number of pre-clinical initiatives are underway or have been started by leading researchers in heart transplantation.</p>
Kidney transplantation 	<p>As with other organs, there is a shortage of transplantable kidneys. Kidneys that are continuously perfused with a solution during transport achieve improved outcomes after transplantation.</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 and Europe. The combination of new perfusion technology with warm perfusion and solutions is the focus of research in the field of organ transplantation.</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 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). Ongoing reports are received from further investigator-driven studies using XVIVO's technology, which regard the application of the technology in different clinical environments. 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 a simple saline solution. 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.</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 three world-leading research teams in xenotransplantation.</p>

Other information

Sustainability

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

XVIVO’s Code of Conduct is our primary sustainability policy. It includes guidelines for business principles, human rights and working principles. For more detailed information regarding our sustainability work, see the company’s Annual Report for 2022. The Annual Report and our key policies are available at www.xvivogroup.com.

Organization and employees

The XVIVO Group has 137 employees, of whom 64 are women and 73 men. Of these, 49 are employed in Sweden and 88 outside Sweden. The head office is located in Gothenburg, Sweden and our subsidiaries are located in Lund, Sweden, the US, Italy, France, Brazil, China, Australia and the Netherlands. XVIVO also has employees based in several other countries in Europe.

Related-party transactions

There were no related-party transactions during the period.

Risk management

XVIVO works continuously to identify, evaluate, and manage risks in different systems and processes. Risk analyses are carried out continuously regarding normal operations and in connection with activities that are outside XVIVO’s regular quality system.

The market risks that are deemed to have a particular impact on XVIVO’s future progress are linked to the availability of financial and medical resources in clinics around the world. Operational risks are risks that limit or prevent XVIVO from developing, manufacturing and selling high-quality, efficient and safe products. The number of organ transplants is marginally affected by seasonal effects. Mainly in new treatment methods, such as warm perfusion of lungs, slightly less activity occurs during the summer months because there is less training and learning during the summer vacation period. Legal and regulatory risks may arise from changes in legislation or policy decisions that may affect the Group’s ability to conduct or develop the business. Financial risks include exchange rate risks.

The crucial strategic risks and operational risks for the Group can be found in the administration report which is part of the Annual Report for 2022, available at www.xvivogroup.com.

Annual General Meeting

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on April 25, 2023 at 3:00 p.m. CEST at the Swedish Exhibition & Congress Centre (Svenska Mässan). The following people have been appointed to be part of XVIVO Perfusion AB’s 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

They were appointed in accordance with the instructions regarding the principles for appointing a Nomination Committee adopted at the Annual General Meeting of XVIVO Perfusion AB (publ) on April 27, 2018. The shareholders who appointed the members of the Nomination Committee jointly represented 32.7 percent of all shares in the company on August 31, 2022.

Outlook

We see continued growing interest in our product and service offering across all organ areas, which paves the way for continued growth. The commercial focus will continue to be on increasing the installed base and the use of our leading perfusion technologies. 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.

In 2023 we will intensify our focus on clinical studies and regulatory approval processes. The goal for the next few 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. We are engaged in positive dialog with the FDA regarding the heart preservation study in the US and we intend to plan for the start of the study as soon as the FDA allows. In 2023 we also intend to commence dialog with the FDA regarding a clinical multicenter trial in the US for Liver Assist. As a result of the increased focus on regulatory studies and product launches, we will continue to invest in our organization, primarily in the US.

Although XVIVO and the transplantation industry in general are making significant progress, there is uncertainty in the wider world. The geopolitical situation unfortunately remains tense. XVIVO currently has very limited sales exposure to Eastern Europe and the procurement chain is not exposed to these markets. 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.

There is a constantly growing need for new organs in the world. At the same time, machine perfusion is becoming an increasingly standard procedure with ever-improving reimbursement systems. As a well-established company with continued strong sales growth, XVIVO looks forward to an exciting 2023.

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.

Gothenburg April 24, 2023

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 Monday, April 24, 2023 at 7.30 am CEST.



Financial calendar

- 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 Interim Report in a conference call at 2.00 p.m. CEST on Monday, April 24.
For access via conference call, click [here](#)
For access via webcast, click [here](#)



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Financial statements

Condensed Consolidated Statement of Net Income

SEK Thousands	January-Mars 2023	January-Mars 2022	January-December 2022
Net sales	140 615	92 654	415 292
Cost of goods sold	-35 798	-27 432	-118 336
Gross profit	104 817	65 222	296 956
Selling expenses	-48 375	-29 519	-152 398
Administrative expenses	-18 985	-14 400	-70 979
Research and development expenses	-26 173	-16 658	-69 343
Other operating income and expenses	-77	-21	2 173
Operating income	11 207	4 624	6 409
Financial income and expenses	5 358	1 565	15 905
Income after financial items	16 565	6 189	22 314
Taxes	-2 389	-1 424	-3 887
Net income	14 176	4 765	18 427
Attributable to			
Parent Company's shareholders	14 176	4 765	18 427
Earnings per share, SEK	0,48	0,16	0,62
Earnings per share, SEK ¹⁾	0,48	0,16	0,62
Average number of outstanding shares	29 831 919	29 498 666	29 525 946
Average number of outstanding shares ¹⁾	29 831 919	29 872 666	29 525 946
Number of shares at closing day	29 831 919	29 498 666	29 831 919
Number of shares at closing day ¹⁾	29 831 919	29 872 666	29 831 919
EBITDA (Operating income before depreciation and amortization)	23 644	14 693	48 576
Depreciation and amortization on intangible assets	-7 633	-6 906	-27 871
Depreciation and amortization on tangible assets	-4 804	-3 163	-14 296
Operating income	11 207	4 624	6 409

¹⁾ After dilution

Consolidated Statement of Total Comprehensive Income

SEK Thousands	January-Mars 2023	January-Mars 2022	January-December 2022
Net income	14 176	4 765	18 427
Other comprehensive income			
Items that may be reclassified to the income statement			
Exchange rate differences	2 881	9 623	65 693
Total other comprehensive income	2 881	9 623	65 693
Total comprehensive income	17 057	14 388	84 120
Attributable to			
Parent Company's shareholders	17 057	14 388	84 120

Condensed Consolidated Statement of Financial Position

SEK Thousands	230331	221231
ASSETS		
Goodwill	626 991	625 319
Capitalized development expenditure	561 574	544 510
Other intangible assets	8 628	8 484
Property, plant & equipment	64 108	47 579
Financial assets	37 717	39 684
Total non-current assets	1 299 018	1 265 576
Inventories	110 549	106 566
Current receivables	132 348	114 397
Liquid funds	197 954	246 545
Total current assets	440 851	467 508
Total assets	1 739 869	1 733 084
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity, attributable to the Parent Company's shareholders	1 446 884	1 430 136
Long-term interest-bearing liabilities	9 605	4 455
Long-term non-interest-bearing liabilities	150 079	163 597
Short-term interest-bearing liabilities	9 040	5 550
Short-term non-interest-bearing liabilities	124 261	129 346
Total shareholders' equity and liabilities	1 739 869	1 733 084

Condensed Consolidated Cash Flow Statement

	January-March 2023	January-March 2022	January-December 2022
Income after financial items	16 565	6 189	22 314
Adjustment for items not affecting cash flow	5 614	6 830	27 510
Paid taxes	-685	-420	199
Change in inventories	-1 957	8 798	-6 325
Change in trade receivables	-14 485	-16 731	-26 860
Change in trade payables	-17 479	-14 013	11 018
Cash flow from operating activities	-12 427	-9 347	27 856
Cash flow from investing activities	-33 526	-52 366	-197 624
Cash flow from financing activities	-2 486	-1 865	-6 842
Cash flow for the period	-48 439	-63 578	-176 610
Liquid funds at beginning of period	246 545	398 696	398 696
Exchange rate difference in liquid funds	-152	4 666	24 459
Liquid funds at end of period	197 954	339 784	246 545

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, 2022	754	1 253 330	22 088	9 278	1 285 450
Total comprehensive income January - March 2022	-	-	9 623	4 765	14 388
Other	-	-	-	48	48
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	-	-300	-	-	-300
Shareholders' equity as of March 31, 2022	754	1 253 030	31 711	14 091	1 299 586
Total comprehensive income April - December 2022	-	-	56 070	13 662	69 732
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	8	59 694	-	1	59 703
Share warrant program	-	1 115	-	-	1 115
Shareholders' equity as of December 31, 2022	762	1 313 839	87 781	27 754	1 430 136
Total comprehensive income January - March 2023	-	-	2 881	14 176	17 057
Other	-	-	-	-309	-309
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	-	-	-	-	-
Shareholders' equity as of March 31, 2023	762	1 313 839	90 662	41 621	1 446 884

Condensed Consolidated Statement of Net Income by quarter

SEK Thousands	Jan-Mar 2023	Oct-Dec 2022	Jul-Sep 2022	Apr-Jun 2022	Jan-Mar 2022	Oct-Dec 2021	Jul-Sep 2021	Apr-Jun 2021
Net sales	140 615	131 514	96 835	94 289	92 654	85 863	54 935	59 263
Cost of goods sold	-35 798	-36 657	-27 464	-26 783	-27 432	-22 873	-16 977	-15 009
Gross profit	104 817	94 857	69 371	67 506	65 222	62 990	37 958	44 254
Selling expenses	-48 375	-45 718	-39 387	-37 774	-29 519	-34 974	-23 530	-22 975
Administrative expenses	-18 985	-23 066	-18 734	-14 779	-14 400	-21 095	-9 049	-14 856
Research and development costs	-26 173	-23 959	-16 651	-12 075	-16 658	-15 476	-10 428	-14 988
Other operating income and expenses	-77	190	744	1 260	-21	255	1 018	-785
Operating income	11 207	2 304	-4 657	4 138	4 624	-8 300	-4 031	-9 350
Financial income and expenses	5 358	447	7 649	6 244	1 565	18 537	2 956	-1 411
Income after financial items	16 565	2 751	2 992	10 382	6 189	10 237	-1 075	-10 761
Taxes	-2 389	-2 017	2 406	-2 852	-1 424	1 952	-54	1 820
Net income	14 176	734	5 398	7 530	4 765	12 189	-1 129	-8 941
Attributable to								
Parent Company's shareholders	14 176	734	5 398	7 530	4 765	12 189	-1 129	-8 941
Earnings per share, SEK	0,48	0,02	0,18	0,26	0,16	0,42	-0,04	-0,31
Earnings per share, SEK ¹⁾	0,48	0,02	0,18	0,26	0,16	0,41	-0,04	-0,31
Average number of outstanding shares	29 831 919	29 602 717	29 512 733	29 512 733	29 498 666	29 241 732	28 727 266	28 727 266
Average number of outstanding shares ¹⁾	29 831 919	29 602 717	29 512 733	29 512 733	29 872 666	29 615 732	29 101 266	29 101 266
Number of shares at closing day	29 831 919	29 831 919	29 561 967	29 561 967	29 498 666	29 498 666	28 752 397	28 752 397
Number of shares at closing day ¹⁾	29 831 919	29 831 919	29 561 967	29 561 967	29 872 666	29 872 666	29 126 397	29 126 397
EBITDA (Operating income before depreciation and amortization)	23 644	13 580	5 904	14 399	14 693	-96	4 181	-1 533
Depreciation and amortization on intangible assets	-7 633	-7 145	-6 891	-6 929	-6 906	-5 336	-5 278	-5 135
Depreciation and amortization on tangible assets	-4 804	-4 131	-3 670	-3 332	-3 163	-2 868	-2 934	-2 682
Operating income	11 207	2 304	-4 657	4 138	4 624	-8 300	-4 031	-9 350

1) After dilution

Consolidated Statement of Total Comprehensive Income by quarter

SEK Thousands	Jan-Mar 2023	Oct-Dec 2022	Jul-Sep 2022	Apr-Jun 2022	Jan-Mar 2022	Oct-Dec 2021	Jul-Sep 2021	Apr-Jun 2021
Net income	14 176	734	5 398	7 530	4 765	12 189	-1 129	-8 941
Other comprehensive income								
Items that may be reclassified to the income statement:								
Exchange rate differences	2 881	-12 173	30 381	37 862	9 623	15 394	3 163	-3 704
Total other comprehensive income	2 881	-12 173	30 381	37 862	9 623	15 394	3 163	-3 704
Total comprehensive income	17 057	-11 439	35 779	45 392	14 388	27 583	2 034	-12 645
Attributable to								
Parent Company's shareholders	17 057	-11 439	35 779	45 392	14 388	27 583	2 034	-12 645

Consolidated Key Ratios

SEK Thousands	January-March 2023	January-March 2022	January-December 2022
Gross margin, %	75	70	72
Gross margin disposables, %	81	79	79
EBIT, %	8	5	2
EBIT (adjusted), %	9	6	3
EBITDA, %	17	16	12
EBITDA (adjusted), %	18	17	14
Net margin, %	10	5	4
Equity/assets ratio, %	83	85	83
Income per share, SEK	0,48	0,16	0,62
Shareholders' equity per share, SEK	48,50	44,06	47,94
Share price on closing day, SEK	244	270	183
Market cap on closing day, MSEK	7 279	7 950	5 459

Condensed Income Statement for the Parent Company

SEK Thousands	January- March 2023	January- March 2022	January- December 2022
Net sales	69 300	61 604	243 737
Cost of goods sold	-11 631	-12 250	-54 599
Gross profit	57 669	49 354	189 138
Selling expenses	-16 732	-14 255	-59 489
Administrative expenses	-17 541	-12 616	-55 691
Research and development expenses	-15 464	-13 174	-52 355
Other operating income and expenses	-112	218	2 324
Operating income	7 820	9 527	23 927
Financial income and expenses	6 644	2 131	19 982
Income after financial items	14 464	11 658	43 909
Taxes	-3 040	-2 545	-9 177
Net income	11 424	9 113	34 732

The Parent Company has no items to be recognized in other comprehensive income and therefore no statement of comprehensive income has been presented. Depreciation/amortization during the period amounts to SEK 4,813 (4,760) thousands.

Condensed Balance Sheet for the Parent Company

SEK Thousands	230331	221231
ASSETS		
Intangible assets	380 792	363 398
Property, plant and equipment	11 517	10 775
Financial assets	935 223	926 531
Total non-current assets	1 327 532	1 300 704
Inventories	32 607	27 548
Current receivables	37 997	36 890
Cash and bank	166 455	196 281
Total current assets	237 059	260 719
Total assets	1 564 591	1 561 423
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity	1 352 991	1 341 567
Provisions	1 680	1 374
Long-term non-interest-bearing liabilities	131 879	137 130
Short-term non-interest-bearing liabilities	78 041	81 352
Total shareholders' equity and liabilities	1 564 591	1 561 423

Notes

Disclosures in accordance with IAS 34.16A are included in the financial statements and notes, as well as elsewhere in the Interim Report.

Note 1. Accounting principles

For the Group, this report is presented pursuant to the Swedish Annual Accounts Act and IAS 34, Interim Financial Reporting, and for the Parent Company pursuant to the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities. Accounting principles applied to the Group and the Parent Company correspond, unless otherwise stated below, to the accounting principles used for the preparation of the latest Annual Report.

Note 2. Financial instruments

The Group's financial assets and liabilities valued at amortized cost amounted to SEK 330 million (429) and SEK 100 million (65) 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 165.5 million (133.4) relating to contingent consideration linked to acquisitions. Contingent considerations are classified under level 3 in accordance with IFRS 13, and measured at fair value with changes recognized in the Income Statement. The calculation of fair value relating to financial liabilities under level 3 affected the Income Statement by SEK -4.9 million (3.7) 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	January-March	January-March	January-December
	2023	2022	2022
Opening balance	170 416	150 676	150 676
Contingent consideration	-	-	26 224
Discounting of contingent consideration	-4 158	-	-
Payment of contingent consideration	-	-20 976	-27 999
Exchange-rate differences	-791	3 696	21 515
Closing balance	165 467	133 396	170 416

Note 3. Net sales

Distribution of net sales

SEK Thousands	January-March							
	Thoracic		Abdominal		Services		Total consolidated	
	2023	2022	2023	2022	2023	2022	2023	2022
Disposables	85 593	59 418	26 039	10 762	-	-	111 632	70 180
Machines	5 321	8 683	4 511	4 304	-	-	9 832	12 987
Service	-	-	-	-	19 151	9 487	19 151	9 487
Net sales	90 914	68 101	30 550	15 066	19 151	9 487	140 615	92 654

Note 4. Consolidated operating segments

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

SEK Thousands	January-March							
	Thoracic		Abdominal		Services		Total consolidated	
	2023	2022	2023	2022	2023	2022	2023	2022
Net sales	90 914	68 101	30 550	15 066	19 151	9 487	140 615	92 654
Cost of goods sold	-15 031	-15 942	-10 807	-6 768	-9 960	-4 722	-35 798	-27 432
Gross profit	75 883	52 159	19 743	8 298	9 191	4 765	104 817	65 222
Gross margin (%)	83	77	65	55	48	50	75	70

Geographical areas

SEK Thousands	January-March							
	Thoracic		Abdominal		Services		Total consolidated	
	2023	2022	2023	2022	2023	2022	2023	2022
North America	55 711	41 518	903	3 181	19 151	9 487	75 765	54 185
South and Latin America	2 231	1 595	-	-	-	-	2 231	1 595
EMEA	23 816	20 771	29 378	9 746	-	-	53 194	30 516
Asia and Pacific	9 156	4 218	269	2 139	-	-	9 425	6 357
Net sales	90 914	68 101	30 550	15 066	19 151	9 487	140 615	92 654

Note 5. Goodwill

TSEK	January-March 2023	January-March 2022	January-December 2022
Opening balance	625 319	460 228	460 228
Acquired goodwill	-	-	112 242
Exchange-rate differences	1 672	7 541	52 849
Closing balance	626 991	467 769	625 319

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 these data enable 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-March 2023	January-March 2022	January-December 2022
Operating income	11 207	4 624	6 409
Depreciation and amortization on intangible assets	7 633	6 906	27 871
Depreciation and amortization on tangible assets	4 804	3 163	14 296
EBITDA (Operating income before depreciation and amortization)	23 644	14 693	48 576

EBITDA (adjusted)

SEK Thousands	January-March 2023	January-March 2022	January-December 2022
EBITDA (Operating income before depreciation and amortization)	23 644	14 693	48 576
Acquisition costs	-	-	8 146
Integration costs	1 244	2 272	6 102
Cash-based incentive programs for employees outside Europe	-	-1 584	-6 372
EBITDA (adjusted)	24 888	15 381	56 452

EBIT (adjusted)

SEK Thousands	January-March 2023	January-March 2022	January-December 2022
EBIT (Operating income)	11 207	4 624	6 409
Acquisition costs	-	-	8 146
Integration costs	1 244	2 272	6 102
Cash-based incentive programs for employees outside Europe	-	-1 584	-6 372
EBIT (adjusted)	12 451	5 312	14 285

Gross profit margin

SEK Thousands	January-March 2023	January-March 2022	January-December 2022
Operating income			
<i>Net sales</i>	140 615	92 654	415 292
Operating expenses			
<i>Cost of goods sold</i>	-35 798	-27 432	-118 336
Gross profit	104 817	65 222	296 956
Gross margin %	75	70	72

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	230331	221231
Shareholders' equity	1 446 884	1 430 136
Total assets	1 739 869	1 733 084
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:

DBD	Donation after brain death.
DCD	Donation after circulatory death.
Evaluation	Evaluation of the function of an organ.
Ex vivo (Latin for "outside a living organism")	Biological processes in living cells and tissues when they are in an artificial environment outside the body. The opposite of in vivo.
EVLP (Ex Vivo Lung Perfusion)	Perfusion of a lung outside the body. The procedure is normally carried out to evaluate a lung before transplantation.
FDA or US Food and Drug Administration	The FDA is the US food and drug authority with responsibility for food, dietary supplements, drugs, cosmetics, medical equipment, radiology equipment, and blood products. FDA approval is required to market a medical device on the US market.
HDE or Humanitarian Device Exemption	A humanitarian device exemption (HDE) application can be submitted to the FDA for a medical device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States per year. An HDE is similar in both form and content to a Premarket Approval (PMA) application but is exempt from the efficacy requirements of a PMA.
Hypothermic non-ischemic perfusion of heart	Circulation of the cooled, dormant donated heart with a supply of oxygen and necessary nutrients during transport to the recipient.
Machine sales	Revenues from the sale or rental of machinery for mechanical perfusion and preservation of organs.
Clinical study/trial	A study in healthy or sick people to examine the effect of a drug or treatment method.
Machine perfusion	New technology that improves preservation and evaluation of organs, which means more organs can be used for transplants. In the Thoracic business area, this includes STEEN Solution™, XPS™, LS™, Lung Assist and Heart Assist as well as other products and services related to the use of those machines. In the Abdominal business area, this includes Kidney Assist Transport, Kidney Assist and Liver Assist as well as other products and services related to the use of those machines.
OPO or Organ Procurement Organization	In the United States, an organ procurement organization (OPO) is a non-profit organization responsible for the evaluation and procurement of deceased-donor organs for organ transplantation. There are approximately 58 such organizations in the United States.
Perfusion	Passage of a fluid through an organ's blood vessels.
PMA or Premarket Approval	Premarket Approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and efficacy of a medical device.
Pre-clinical study	Research performed before a drug or method of treatment is sufficiently documented to be studied in humans.
Preservation	Storage and maintenance of an organ outside the body before transplantation.
Reimbursement	Reimbursement is used in the health insurance system to enable healthcare providers to be reimbursed faster and more easily for accrued expenses from a private or public insurance company (in the United States, e.g. Medicare).
Static preservation	Static preservation refers to preservation methods where the organ is cooled during transport and before transplantation. In the Thoracic business area, this 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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