



REPORT ON OPERATIONS 2020

XVIVO PERFUSION AB (PUBL)

XVIVO Perfusion is a medical technology company which develops and markets solutions and systems for assessing the usability of organs, enabling the treatment of organs, and maintaining organs in good condition outside of the body, pending transplantation. The company is active in all major solid organ areas and consists of two business areas: Thoracic (heart and lung) and Abdominal (liver and kidney). In lung transplantation, the company's product Perfadex® Plus has a market share of approximately 90 percent in the traditional static preservation of lungs for transplantation. The company's products for warm perfusion, XPS™ and STEEN Solution™, have regulatory approval in all major markets, and were the first products that received regulatory approval from the FDA for warm perfusion of marginal lungs. In liver and kidney transplantation, XVIVO Perfusion develops and sells machine perfusion products, which in clinical studies have shown increased organ survival rates. XVIVO Perfusion also develops the next generation of pre-transplant heart storage products that aim to store and transport the heart from a donor in an optimized way, through non-ischemic heart preservation.

XVIVO Perfusion employs around 80 people at its headquarters in Gothenburg, Sweden, its offices in Lund, Sweden, Groningen, Netherlands, and its office for North & South America in Denver, CO, USA. The XVIVO share is listed on NASDAQ Stockholm and has the ticker symbol XVIVO.



SIGNIFICANT PROGRESS IN A CHALLENGING YEAR

FOURTH QUARTER 2020 (OCT - DEC)

Financial information

- In the fourth quarter, XVIVO presents sales from the new business area Abdominal, which includes kidney and liver transplants. The business area performed well and contributed with an acquired growth in total net sales (incl. durable goods) of 26 percent in local currency. The business area Thoracic (heart and lung transplants) decreased net sales by 25 percent in local currency.
- Total net sales (incl. durable goods) in the quarter amounted to SEK 60.3 (62.4) million, corresponding to a decrease by 3 percent in SEK and an increase by 2 percent in local currency. Net sales of non-durable goods* in the quarter amounted to SEK 55.0 (59.4) million, corresponding to a decrease by 8 percent in SEK and a decrease by 2 percent in local currency.
- Sales from machine perfusion** represented 57 percent (51) of total net sales and 52 percent (48) of sales of non-durable goods.
- Operating income before depreciation and amortization (EBITDA), adjusted for costs for a share-based bonus program for employees outside Sweden and integration costs, amounts to SEK 6.8 (8.3) million, corresponding to a positive EBITDA margin of 11 percent (13). Reported EBITDA amounted to SEK -6.5 (8.5) million corresponding to an EBITDA margin of -11 percent (14).

- Operating income (EBIT) amounted to SEK -14.3 (1.6) million, after depreciation and amortization of SEK 7.8 (6.9) million. Adjusted for the above-mentioned specific costs, operating profit amounted to SEK -1.0 million (1.4).
- Net income amounted to SEK -19.6 (-1.9) million, resulting in earnings per share of SEK -0.68 SEK (-0.07).
- Cash flow from operating activities during the quarter amounted to SEK -22.0 (-7.2) million, primarily as a result of payments of acquired operating liabilities in Organ Assist and integration costs relating to the acquisition. Cash flow from investing activities amounted to SEK -222.2 (-26.3) million, of which SEK -201.3 million relates to the acquisition of Organ Assist. Cash and cash equivalents at the end of the quarter amounted to SEK 354.2 (160.0) million.

Significant events

- The scientific journal The Lancet published the results of a European study showing better survival of transplanted kidneys after cold machine perfusion with added oxygen. The technology used in the study is CE marked and XVIVO during 2021 intends to submit an application to the FDA, whose approval would enable a launch in the US market.
- The first patient in XVIVO's European Heart preservation study was transplanted. The patent protected heart preservation device, developed by Professor Stig Steen and commercialized by XVIVO, uses a novel technique for preservation of the donor heart during transport.
- On an extraordinary general meeting, Lars Henriksson and Lena Höglund were appointed as new members of the Board of Directors.

EXPANDED OPERATIONS

Business areas

Following the acquisition of Organ Assist and as of the fourth quarter of 2020, XVIVO's operations will be conducted in two business areas: Thoracic (lung and heart transplantation) and Abdominal (liver and kidney transplantation). Within each business area, both sales and R&D take place.

Segments and product categories

XVIVO follows up sales and gross profit in two segments: Sales of durable goods and Sales of non-durable goods.

The financial reporting also states how sales are divided into the product categories machine perfusion, static preservation and other sales. For definitions, see page 19.

THE PERIOD 2020 (JAN - DEC)

Financial information

- Total net sales (incl. durable goods) in the period amounted to SEK 179.9 (220.8) million, corresponding to a decrease by 19 percent in SEK and 17 percent in local currency. Net sales of non-durable goods* in the period amounted to SEK 169.4 (206.9) million, corresponding to a decrease by 18 percent in SEK and 16 percent in local currency. The business area Thoracic decreased by 24 percent in local currency. Business area Abdominal performed well and contributed with an acquired growth in total net sales (including durable goods) of 7 percent in local currency.
- Sales from machine perfusion** represented 43 percent (48) of total net sales and 40 percent (45) of sales of non-durable goods.
- Operating profit before depreciation and amortization (EBITDA), adjusted for costs associated with organizational change, cost reservation for the share-based bonus programs for employees outside Sweden as well as integration and acquisition costs, amounts to SEK 20.2 million (35.8), corresponding to an EBITDA margin of 11 percent (16). Reported operating profit before depreciation and amortization (EBITDA) amounted to SEK -15.6 million (28.8), corresponding to an EBITDA margin of -9 percent (13).
- Operating income (EBIT) amounted to SEK -45.7 (3.9) million, after depreciation and amortization of SEK 30.0 (24.9) million. Adjusted for the above-mentioned specific costs, operating profit amounted to SEK -9.9 million (10.9).
- Net income amounted to SEK -43.7 (4.9) million, resulting in earnings per share of SEK -1.61 (0.19).
- Cash flow from operating activities during the period amounted to SEK -12.3 (29.5) million, primarily as a result of payments of acquired operating liabilities in Organ Assist and acquisition- and integration costs relating to the acquisition. Cash flow from investing activities amounted to SEK -266.5 (-83.8) million, of which SEK -201.3 million relates to the acquisition of Organ Assist. Cash flow from financing activities amounted to SEK 482.8 million (25.6) net and is primarily explained by a directed share issue of SEK 500 million less issuance costs of SEK 13.0 million. Cash and cash equivalents at the end of the period amounted to SEK 354.2 (160.0) million.

Significant events

- In September, XVIVO entered into an agreement to acquire 100 percent of the shares in the Dutch medical technology company Organ Assist B.V. Organ Assist focuses mainly on developing machines and consumables for perfusion of liver and kidney. Through the acquisition, XVIVO became the first company in the world who actively conducts business within preservation and evaluation of organs in all major organ areas. The acquisition accelerated the company's strategy to become a global supplier of solutions

and systems in all major organ areas. The purchase price amounted to a maximum of EUR 24 million, with an initial payment of EUR 20 million and a conditioned, additional purchase price of maximum EUR 4 million.

- The acquisition of Organ Assist was financed through a directed share issue. Investors included both existing and new shareholders, including Bure Equity AB, Swedbank Robur, Eccenovo AB (publ.), Fjärde AP-Fonden, Lannebo Fonder and Handelsbanken Fonder. The issue took place with no discount at a subscription price of SEK 236 and the company received approximately SEK 500 million. Issuance costs amounted to SEK 13.0 million.
- Dag Andersson was appointed new President and CEO in April and took office in June. XVIVO Perfusion's founder and former CEO, Magnus Nilsson, remains as Senior Advisor to primarily work with R&D.
- A reorganization was carried out with the aim of creating a more efficient and successful organization. The Management Team was strengthened with a new Commercial Director, Johan Holmström and a new R&D Director Charlotte Walldal. Furthermore, the company's CFO, Christoffer Rosenblad, was appointed to a newly established position within XVIVO as Chief Operating Officer; COO. Kristoffer Nordström, XVIVO's previous Finance Manager, was appointed as new CFO. Anne-Li Sigvardsson, MSc, was appointed IP Manager (Chief Intellectual Property Officer). Andreas Wallinder, MD, PhD was appointed Chief Medical Officer.
- The first patient in the extended PrimeECC® study was included.
- During the period, the scientific journal Nature Communications published an article describing the company's heart preservation technology and showing the method is safe.
- The further developed and more user-friendly Perfadex® Plus with Click Port was launched worldwide.
- AKH University Hospital in Vienna, Austria, which is one of the three largest lung transplant clinics in Europe, purchased an XPS™. An XPS™ was, for the first time, sold to a paediatric (children's) hospital in Rome, Italy. At the end of the period, 54 clinics world-wide had access to XPS, LS or LS™.
- The application period for warrant program for employees series 2020/2022 expired on September 23 and a total of 374,000 warrants were subscribed for.

CEO'S COMMENTS



For XVIVO, 2020 was a successful year in several respects. A new management team was appointed during the year and a strategy set for 2025 was launched. There is now a clear and distinct plan for how XVIVO will continue to grow profitably in the coming years and become an even stronger player in

the transplant area.

In September, we acquired an exciting Dutch company, Organ Assist, active primarily in machine preservation of liver and kidney. The acquisition means that we can now address all major organ areas. Of all organs that are transplanted annually, the lung and heart account for 10 percent and the kidney and liver for 88 percent.

Evidence of the strong confidence in XVIVO and the company's strategy was shown not least in connection with the autumn's successful raising of capital, when the company's ownership base was strengthened and broadened.

Sales and EBITDA

Our sales were affected negatively by the COVID-19 pandemic from the second quarter onwards. Elective care in the form of planned operations was downgraded in large parts of the world, which also affected transplant operations. At the beginning of the third quarter, however, we were able to notice a recovery that contributed to total net sales for the full year amounting to SEK 180 million (221).

For the fourth quarter, total net sales amounted to SEK 60 million, compared with SEK 62 million the previous year. Net sales of non-durable goods amounted to SEK 55 million (59), which meant a decrease of 2 percent in local currency compared with the same quarter last year. Sales within our new business area Abdominal (products in liver and kidney) reached an "all time high" during the quarter and amounted to SEK 17 million. This bodes well for the future and confirms the importance of the acquisition we have made. The quarter's EBITDA, adjusted for costs relating to the issue of warrants for employees outside Sweden and integration costs attributable to acquisitions, amounted to SEK 7 million. This corresponds to an EBITDA margin of 11 percent (13), which correlates to the adjusted margin for the year of 11 percent. This is strong considered the challenges that the pandemic has brought to the global health care.

It is my belief that we will have to live with the reality that the pandemic brings for a large part of 2021. We have an ambitious commercial plan for the full year, but should expect that 2021 will start weaker than a normal year, then gradually increase in conjunction with the recovery of the global transplant industry.

Research and Development

In 2021, we intend to increase investments in R&D more than we have done in any previous year. We have several prioritized projects underway. The clinical studies linked to our

heart project started during the fourth quarter with recruitments of patients in both Belgium and Sweden.

Another very interesting advance in research was highlighted in an article published in the prestigious scientific journal, *The Lancet*, this autumn. The article shows that oxygenated perfusion of kidneys using XVIVO's products during transport to the hospital has a significant positive impact on first-year results after transplantation. The researchers found that in the group with oxygenated perfusion, significantly fewer patients lost kidney function completely after transplantation, only 3 percent compared to 10 percent in the group that did not receive this treatment. A goal during 2021 is that we will launch the kidney transport unit that made these good results possible in the study.

New brand platform

In 2021, there will also be important changes in our brand platform and in our brand guidelines. As a consequence of the acquisition of Organ Assist, we must have a platform and visual identity that clearly shows that the new XVIVO has machines and solutions for all significant organs.

As I wrote in my CEO's comments for the second quarter of 2020, I am very impressed with the high competence and the strong commitment that characterizes the organization. It has been a very rewarding year for me as CEO and I look forward to continuing to develop the company together with all of my colleagues. In 2020, the organization has been strengthened in several areas. Sales resources have been added in North America, Europe and China. The R&D organization has been strengthened to ensure the delivery of the projects that we prioritize.

Priorities 2021

I would like to end my CEO's speech by mentioning our priorities for 2021:

- The integration of Organ Assist with a focus primarily on ensuring that the entire sales organization can handle our more complete range of machines and solutions for all major organ areas.
- The heart studies have begun in Europe and are also expected to begin in the USA and Australia during the first half of this year.
- The goal is to obtain FDA-approval for the oxygenated kidney transport unit in Europe and North America. We are convinced that there is great potential in this product.
- The ambition to continue with strategic price adjustments remains. We will raise prices in 2021 for our entire range and thereby ensure continued great margins on our products.

We will also work with improvements related to our lung machine platform. Our current machine, XPS, which is used in connection with warm perfusion of lungs, will be upgraded. We will also launch the machine (Lung Assist) that Organ Assist has developed, and which is a less integrated but also cheaper machine for lung perfusion.

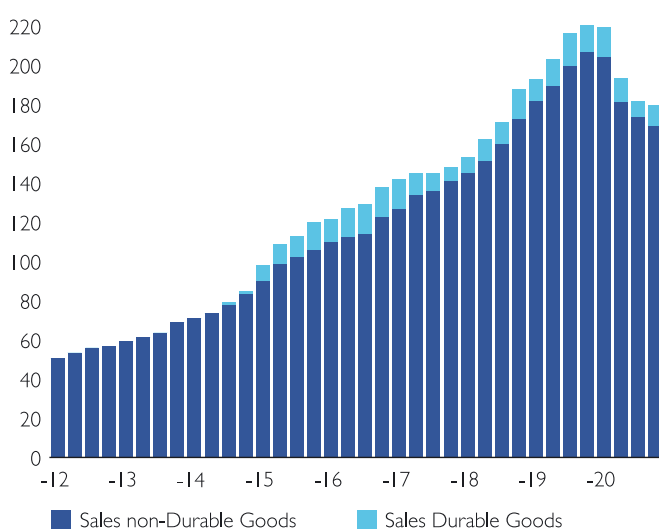
Dag Andersson
CEO

FOURTH QUARTER 2020 (OCTOBER - DECEMBER)

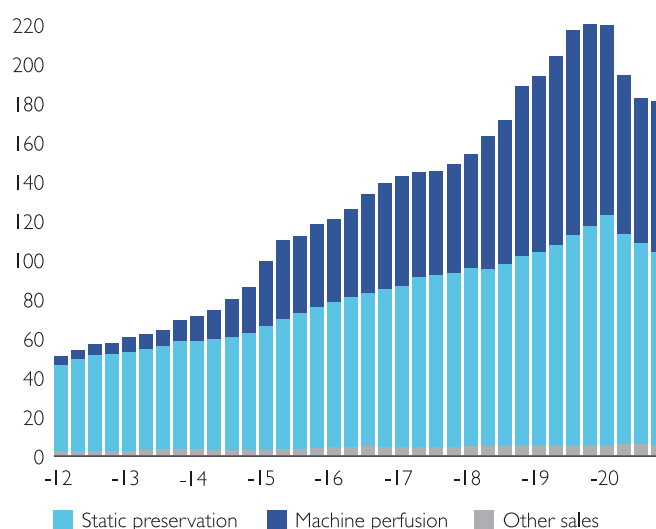
Net Sales and gross margin

The Covid-19 pandemic continued to have an impact on sales during the fourth quarter, primarily in the business area Thoracic and the sales relating to machine perfusion used in lung

**NET SALES
ROLLING 12 MONTHS (SEK MILLIONS)***



**NET SALES (INCL. DURABLE GOODS)
ROLLING 12 MONTHS (SEK MILLIONS)**



COMPILATION OF NET SALES AND EBITDA

SEK THOUSANDS	January - December 2019		October - December 2019	
	2020	2019	2020	2019
Net Sales non-Durable Goods	169 425	206 857	54 927	59 401
Net Sales Durable Goods	10 436	13 980	5 350	3 015
Net Sales Total	179 861	220 837	60 277	62 416
Cost of Goods non-Durable Goods	-38 980	-47 439	-15 143	-13 771
Cost of Goods Durable goods	-7 906	-10 585	-3 777	-2 939
Cost of Goods Total	-46 886	-58 024	-18 920	-16 710
Gross income non-Durable Goods	130 445	159 418	39 784	45 630
Gross margin non-Durable Goods, %	77%	77%	72%	77%
Gross income Durable Goods	2 530	3 395	1 573	76
Gross income Total	132 975	162 813	41 357	45 706
Gross margin Total, %	74%	74%	69%	73%
Selling expenses	-59 899	-60 786	-19 229	-18 372
Administrative expenses	-30 342	-24 739	-11 163	-7 152
Research and development costs	-56 178	-62 651	-15 886	-17 964
Other operating revenues and expenses**	-32 231	-10 697	-9 406	-622
Operating Income	-45 675	3 940	-14 328	1 596
Depreciation of cost of goods sold	-462	-815	180	-208
Depreciation of administrative expenses	-3 154	-2 216	-754	-631
Amortization of research and development expenses	-21 133	-16 624	-6 070	-4 693
Depreciation of other operative expenses	-5 289	-5 205	-1 178	-1 351
EBITDA	-15 637	28 800	-6 506	8 479
EBITDA, %	-9%	13%	-11%	14%

EBITDA for the period October - December 2020 has been affected by costs amounting to SEK 13.2 million for the share-based incentive program for employees outside Sweden and costs for reorganization and integration. Adjusted for these costs, EBITDA for the period amounted to SEK 6.8 million (8.3), corresponding to an EBITDA margin of 11 (13) percent. For the period January-December 2020, EBITDA, adjusted for these cost types, amounted to SEK 20.2 million (35.8), corresponding to an EBITDA-margin of 11 percent (16).

Total net sales (incl. durable goods) in the quarter amounted to SEK 60.3 (62.4) million, corresponding to a decrease by 3 percent in SEK and an increase by 2 percent in local currency. Net sales of non-durable goods* in the quarter amounted to SEK 55.0 (59.4) million, corresponding a decrease by 8 percent in SEK and a decrease by 2 percent in local currency. The business area Thoracic decreased net sales by 25 percent in local currency. Business area Abdominal performed well and contributed with an acquired growth in total sales (including durable goods) of 26 percent in local currency.

Sales from machine perfusion** represented 57 percent (51) of total sales and 52 percent (48) of sales of non-durable goods. Static preservation and other sales represented the remaining share of sales.

The total gross margin during the quarter was 69 (73) percent. The decrease is primarily explained by the fact that the business area Abdominal has lower margins than Thoracic, and a change in product mix (higher share sales of durable goods). The gross margin for non-durable goods during the quarter was 72 (77) percent. This decrease is also primarily explained by lower margins in the Abdominal area.

Thoracic

Total net sales during the quarter amounted to 43.7 (62.4) million, corresponding to a decreased by 30 percent in SEK and 25 percent in local currency. Net sales of non-durable goods* in the quarter amounted to SEK 41.1 (59.4) million, corresponding to a decrease by 31 percent in SEK and 26 percent in local currency.

Sales from machine perfusion** represented 40 percent (51) of total net sales and 36 percent (48) of sales of non-durable goods. Static preservation and other sales represented the remaining share of sales.

The total gross margin during the quarter was 76 (73) percent. The gross margin for non-durable goods during the quarter was 80 (77) percent. The increase is primarily explained by a change in product mix with a lower share of sales from machine perfusion.

Abdominal

Total net sales during the quarter amounted to 16.6 (-) million. Net sales of non-durable goods* in the quarter amounted to SEK 13.9 (-) million. Net sales of durable goods in the quarter amounted to SEK 2.7 (-) million. All sales relate to machine perfusion.

The total gross margin during the quarter was 48 (-) percent. The gross margin for non-durable goods during the quarter was 50 (-) percent and the gross margin for durable goods was 41 (-) percent.

Income

During the quarter, operating income before depreciation and amortization (EBITDA) was affected by costs for a share-based

bonus program for employees outside Sweden of SEK 8.3 million and integration costs of SEK 4.9 million. Adjusted for these costs, the company reported an EBITDA for the quarter of SEK 6.8 (8.3) million, corresponding to a positive EBITDA margin of 11 percent (13). Reported operating income before depreciation and amortization (EBITDA) amounted to SEK -6.5 (8.5) million corresponding to an EBITDA margin of -11 percent (14).

Operating income (EBIT) amounted to SEK -14.3 (1.6) million, after depreciation and amortization of SEK 7.8 (6.9) million. Adjusted for the above-mentioned specific costs, operating profit amounted to SEK -1.0 million (1.4).

Selling expenses in relation to sales for the quarter amounted to 32 percent (29) as fixed costs such as personnel costs were not reduced in relation to the reduced sales. The company has been able to maintain good activity in its marketing initiatives, whereby no furlough has been justified. R&D costs amounted to 26 percent (29) of sales. The decrease is explained by more distinct priorities in the development projects. Administrative expenses amounted to 19 percent (11) of sales, primarily relating to integration costs.

Other operating revenues and expenses, net, during the quarter amounted to SEK -9.4 (-0.5) million. The item consists primarily of costs for a share-based incentive program for employees outside Sweden, SEK -8.3 million. The remaining part consists primarily of exchange rate translation effects. See note 4 for more information.

Financial income and expenses, net, for the quarter amounted to SEK -11.6 million (-3.8). The increase is due to a stronger Swedish krona and its impact on exchange rate conversions in cash and cash equivalents.

During the quarter, SEK 18.9 (17.6) million of the development costs were capitalized as an intangible asset. SEK 12.8 (14.4) million was attributable to investments in the heart preservation project, SEK 3.9 (-) was attributable to investments in abdominal projects, SEK 0.2 (2.1) million was attributable to PrimECC and SEK 2.0 (1.1) million was attributable to product development of the rest of the product portfolio. Amortization of capitalized development costs for the quarter amounted to SEK 5.1 (3.9) million, of which SEK 3.9 (3.9) million was attributable to amortization of capitalized development costs for regulatory approvals for products within lung transplantation.

Cash flow

Cash flow from operating activities during the quarter amounted to SEK -22.0 (-7.2) million, primarily as a result of payments of acquired operating liabilities in Organ Assist and integration costs relating to the acquisition. Cash flow from investing activities amounted to SEK -222.2 (-26.3) million, of which -201.3 relates to the acquisition of Organ Assist. SEK -19.7 (-18.8) million was invested in intangible assets and SEK -0.8 (-7.4) million was invested in tangible assets. Cash flow from financing activities amounted to SEK -1.7 (-0,1) million net. Exchange rate

* See note 3 for revenue per segment ** See page 19 Glossary for definitions

differences in cash and cash equivalents had a negative effect on cash flow for the quarter of SEK -8.2 million (-3.5). Cash and cash equivalents at the end of the quarter amounted to SEK 354.2 (160.0) million.

SIGNIFICANT EVENTS DURING THE QUARTER

First patient in the European Heart Preservation study was transplanted

The first patient in XVIVO's European Heart preservation study was transplanted during the month of November. The patent protected Heart Preservation device, developed by Professor Stig Steen and commercialized by XVIVO, uses a novel technique for preservation of the donor heart during transport. Nine European transplant centers will include a total of 202 patients in the trial that forms the basis of a European regulatory approval application and will investigate if the new technology can improve patient outcome and reduce complications after heart transplantation.

Publication in The Lancet shows better survival of transplanted kidneys after cold machine perfusion with oxygen

In November, a study was published in the scientific journal The Lancet that shows that oxygenated perfusion of kidneys before transplantation has a significant impact on the first-year result after transplantation: less graft failure, better function and lower rejection of the kidney when compared to cold perfusion alone. The randomized trial, with kidneys aged 50 years or older, donated after circulatory death, was performed in 19 European transplant centers and included 212 patients. The technology used in the study is CE-marked and XVIVO intends to submit an application during 2021 to the FDA, whose approval is required to enable a launch in the US market.

New board members elected

On the extraordinary general meeting held on October 14, 2020, Lars Henriksson and Lena Höglund were elected as new members of the board. Dag Andersson left the board as a result of his appointment as a CEO and President during the second quarter.

THE PERIOD 2020 (JANUARY - DECEMBER)

Net Sales and gross margin

The Covid-19 pandemic continued to have an impact on sales during the fourth quarter, primarily in the business area Thoracic and the sales relating to lung transplants. During March, April and May, the decline was substantial. After the summer months, which normally involve somewhat lower activity, some recovery has taken place in the more important markets. The decline in lung transplants has mainly been due to the extent to which the Covid-19 pandemic has affected intensive care in the various markets. The business area Abdominal has not been affected to the same extent.

Total net sales (incl. durable goods) in the period amounted to SEK 179.9 (220.8) million, corresponding to decrease by 19 percent in SEK and 17 percent in local currency. Net sales of non-durable goods* in the period amounted to SEK 169.4 (206.9) million, corresponding to a decrease by 18 percent in SEK and 16 percent in local currency. The business area Thoracic decreased by 24 percent in local currency. Business area Abdominal performed well and contributed with an acquired growth in total sales (including durable goods) of 7 percent in local currency.

Sales from machine perfusion** represented 43 percent (48) of total sales and 40 percent (45) of sales of non-durable goods. Static preservation and other sales represented the remaining share of sales. Sales within Thoracic was affected during the period partly because fewer EVLPs were being performed in general and partly due to delays in partner projects. Within Thoracic, sales from machine perfusion** represented 38 percent of total sales and 35 percent of sales of non-durable goods. Within Abdominal, all sales relate to machine perfusion.

The total gross margin during the period was 74 (74) percent. The gross margin for non-durable goods during the period was 77 (77) percent.

The total gross margin during the period for business area Thoracic was 77 (74) percent. The gross margin for non-durable goods during the quarter was 79 (77) percent. The increase is primarily explained by a change in product mix with a lower share of sales from machine perfusion. The total gross margin during the period for business area Abdominal was 48 (-) percent. The gross margin for non-durable goods during the quarter was 50 (-) percent and the gross margin for durable goods was 41 (-) percent.

Income

Operating income before depreciation and amortization (EBITDA) during the period was charged with costs associated with organizational change of SEK 9.9 million, cost reservation for the share-based bonus programs for employees outside Sweden of SEK 18.3 million, integration costs of SEK 4.9 million and acquisition costs of SEK 2.7 million. Adjusted for these specific costs of a total of SEK 35.8 million, EBITDA for the period amounts to SEK 20.2 million (35.8), corresponding to an EBITDA margin of 11 percent (16). Operating income before depreciation and amortization (EBITDA) amounted to SEK -15.6 (28.8) million, corresponding to an EBITDA margin of -9 (13) percent.

Operating income (EBIT) amounted to SEK -45.7 (3.9) million, after amortization and depreciation of SEK 30.0 (24.9) million. Adjusted for the above-mentioned specific costs, operating profit amounted to SEK -9.9 million (10.9).

As previously communicated, the company followed a cost reduction program. Variable costs, such as consulting and travel costs, were reduced during the period. In relation to sales, however, the company's total costs increased during the period when certain fixed costs such as personnel costs were not reduced in

* See note 3 for revenue per segment ** See page 19 Glossary for definitions

relation to the reduced sales, and because of recruitments for the purpose of building a strong organization to support the long-term goals of the company. Government support has been received in the USA and Australia of SEK 4.2 million, which has been reported as reduced personnel costs, primarily in the sales and R&D functions. Selling expenses in relation to sales during the period was 33 percent (28). R&D expenses amounted to 31 percent (28) of sales. Administrative expenses amounted to 17 percent (11) of sales. Adjusted for integration and acquisition costs, administrative expenses amounted to 15 percent of sales.

Net of other operating revenues and expenses during the period was SEK -32.2 (-10.7) million. The increase is mainly explained by costs associated with organizational change of SEK 9.9 million, cost reservation for the share-based bonus programs for employees outside Sweden of SEK 18.3 million and negative currency translation effects. See note 4 for more information.

During the period, SEK 60.5 (69.8) million of the development costs were capitalized as intangible assets. SEK 49.5 (52.7) million was attributable to investments in the heart preservation project, SEK 3.9 (-) was attributable to investments in abdominal projects, SEK 3.0 (4.2) million was attributable to PrimECC® and SEK 4.1 (2.9) million was attributable to product development in the rest of the product portfolio. Amortization of capitalized development costs for the period amounted to SEK 16.7 (13.7) million, of which SEK 15.5 (13.4) million was amortization of capitalized development cost for regulatory approvals for the products in lung transplantation.

Cash flow

Cash flow from operating activities during the period amounted to SEK -12.3 (29.5) million, primarily as a result of payments of acquired operating liabilities in Organ Assist and acquisition- and integration costs relating to the acquisition. Cash flow from investment activities amounted to SEK -266.5 (-83.8) million, of which SEK -201.3 million relates to the acquisition of Organ Assist. SEK 62.0 (73.2) million was invested in intangible assets and SEK 2.6 (10.5) million was invested in tangible assets. Cash flow from financing activities amounted to SEK 482.8 (25.6) million net. The increase is primarily explained by funds raised through the directed share issue of SEK 500 million, less issuance cost of SEK 13.0 million and amortization of lease liabilities of SEK 5.7 million. Exchange rate differences in cash and cash equivalents had a negative effect on cash flow for the period of SEK -9.7 million (1.7). Cash and cash equivalents at the end of the period amounted to SEK 354.2 (160.0) million.

Financing

XVIVO Perfusion's equity / assets ratio is strong and amounted to 88 percent (91) at the end of the period. The company's total credit facilities consist of an overdraft facility and it amounted to SEK 30 (30) million at the end of the period, of which SEK 0.0 million (0.0) was utilized.

SIGNIFICANT EVENTS DURING THE PERIOD

XVIVO completes the acquisition of the Dutch medical technology company Organ Assist B.V

On September 23, XVIVO entered into an agreement to acquire 100 percent of the shares in the Dutch medical technology company Organ Assist B.V. Organ Assist focuses mainly on developing machines and consumables for perfusion of liver and kidney. Through the acquisition, XVIVO became the first company in the world who actively conducts business within preservation and evaluation of organs in all major organ areas. The acquisition accelerates the company's strategy to become a global supplier of solutions and systems in all major organ areas. The purchase price amounted to a maximum of EUR 24 million, with an initial payment of EUR 20 million and a conditioned, additional purchase price of maximum EUR 4 million. The additional payments are divided between two different payments of SEK 2 million each, where one is dependent on sales targets for 2021 and the other on regulatory FDA approval for the kidney transport device.

Directed share issue in connection with the acquisition raised SEK 500 million

The acquisition of Organ Assist was financed through a directed share issue which took place in the same day as the acquisition. Investors included both existing and new shareholders, including Bure Equity AB, Swedbank Robur, Eccenovo AB (publ.), Fjärde AP-Fonden, Lannebo Fonder and Handelsbanken Fonder. The issue took place without discount at a subscription price of SEK 236 and the company raised approximately SEK 500 million. Issuance costs amounted to SEK 13.0 million. The number of shares and votes in XVIVO Perfusion AB (publ) was increased by 2,118,640 shares and amounts to 28,719,136.

Organizational changes

Dag Andersson was appointed as the new President and CEO in April and took office in June. XVIVO Perfusion's founder and former CEO, Magnus Nilsson, remains as Senior Advisor to primarily work with R&D. Dag has a background in healthcare as CEO of Diaverum AB from 2008 up until 2018 and before that worked for 15 years in leading positions at the medical technology company Mölnlycke Health Care.

A reorganization, which affected the company's management team and all departments, has taken place with the aim of creating a more efficient and focused organization. The management team has been strengthened with a new Commercial Director, Johan Holmström, and a new R&D Director, Charlotte Walldal. Furthermore, the company's current CFO, Christoffer Rosenblad on December 1st, was appointed to a newly established position within XVIVO as Chief Operating Officer, COO. Kristoffer Nordström, XVIVO's previous Finance Manager, was appointed as new CFO.

Anne-Li Sigvardsson, MSc has been appointed Chief Intellectual Property Officer (CIPO). Anne-Li is responsible for the company's IP portfolio and has developed XVIVO Perfusions patent

portfolio for PrimECC and Perfadex Plus, among other products. Andreas Wallinder, MD, PhD has been appointed Chief Medical Officer (CMO). Andreas is the indication leader for the company's heart preservation development and clinically responsible within the company.

First patient in the extended PrimECC® study included

PrimECC®, a CE-marked and patent-protected product, is developed to reduce complications after heart surgery. PrimECC® is a solution used to prime the heart-lung machine before open heart-surgery. Hundreds of thousands of heart surgeries are performed today each year worldwide using a heart-lung machine. The extended study that has now begun intends to expand and strengthen the clinical documentation for PrimECC® and will include a total of 366 patients.

Heart preservation study from Lund published in Nature Communications

During the period, the scientific journal Nature Communications published an article written by Professor Johan Nilsson, describing the use of XVIVO Perfusion's heart preservation technology developed by Professor Stig Steen. The results from the study show that our method is safe and functional for clinical use.

Perfadex® Plus with Click Port launched globally during the first quarter

As XVIVO Perfusion has previously reported, the company has developed a new, 'ready to use' version for cold preservation of lungs, called Perfadex® Plus. The advantage of Perfadex® Plus is that it is ready to use and the clinic does not need to add buffer and calcium ions before use. The product is now available in all major markets globally. Patent applications for Perfadex® Plus have been filed in all major markets and in 2019 the European Patent Office approved the patent for Perfadex® Plus in Europe.

XPS™ sold to leading European lung transplant clinic and pediatric clinic

The AKH University Hospital in Vienna, Austria, which is one of the three largest lung transplant clinics in Europe, has purchased an XPS™. Furthermore, a paediatric transplant clinic in Rome, Italy has purchased an XPS™. This is the first XPS™ delivered to a children's hospital.

Warrants program 2020/2022 finalized

The application period for warrants program for employees series 2020/2022 expired on September 23, 2020 and a total of 374,000 warrants were subscribed for.

OUTLOOK FOR 2021

In 2020, XVIVO has been affected by the ongoing Covid-19 pandemic through the reduction in transplants. Available healthcare resources have largely focused on Covid-19 patients and thus the number of donated organs has decreased and waiting lists have increased. During March to May, the decline was substantial. The important markets, the USA and Europe, gradually recovered

during the third quarter. The extent of the impact on sales during 2021 will depend on the extent to which the Covid-19 pandemic affects intensive care in these markets. Transplantation is a life-sustaining treatment and transplants are prioritized by health authorities around the world. For this reason, the company estimates that the number of transplants, and thus the demand for XVIVO's products, will continue to increase long-term.

The company will intensify its efforts to receive regulatory approval of the Kidney Assist Transport device in the USA, which is the company's product for improved kidney transport. In 2020, very good study results were published in the Lancet which shows the benefits of XVIVO's technology, and the company aims to apply for 510K approval to the FDA in 2021. Costs for regulatory approval in the US will be capitalized on an on-going basis.

The company will continue to focus heavily on clinical studies and product development in all major organ areas. In heart transplantation, the goal is to make great progress in the clinical multi center studies in Europe, the USA and Australia. In kidney transplantation, the goal is to obtain regulatory approval in the USA for the kidney transport device during the second half of 2021. The PrimECC® study in Sweden should be able to pick up speed as the pressure on intensive care decreases.

THE COMPANY IN BRIEF

Background

Organ transplantation is the last resort for patients with end-stage organ failure. There is an acute global shortage of donated organs which results in deaths among patients on the waitlist. At the same time many donated organs are deemed unsuitable for transplantation and go unutilized.

Operations

XVIVO Perfusion AB is a medical technology that addresses the global shortage of donated organs by developing, manufacturing and commercializing products for optimal storage during transportation, assessment and treatment of organs outside of the body, ensuring the safe use of more organs and ultimately giving more patients the chance of a life-saving transplant. Since 2020, the company is active in all major solid organ areas. In lung transplantation, the company's product Perfadex® Plus has a market share of approximately 90 percent in the traditional preservation of lungs.

Thoracic

A great problem in transplantation healthcare is the lack of available lungs. Currently, in the company's largest market, the USA, only around 20 percent of the available donated lungs are transplanted, as it is considered far too risky to transplant the remaining majority. By using XVIVO's product STEEN Solution™, the organ is cleared of harmful substances from the donor, thus creating a better environment for the organ's cells. The technology thereby allows the organ to "recover" when possible. It also allows for functional testing to be performed on the organ outside of the body. In clinical use in the USA,

Europe, Australia, and Canada, it has become apparent that once STEEN Solution™ perfusion has been carried out, many of the organs that were initially “rejected” are assessed as being usable and have been successfully transplanted into patients with end-stage lung disease. Therefore, the use of STEEN Solution™ has the potential to increase the total number of lung transplants. The company’s products for warm perfusion, XPS™ and STEEN Solution™, have regulatory approval in all major markets in the world, and were the first products to receive regulatory approval from the FDA for warm perfusion of marginal lungs.

Based on the world leading research of Professor Stig Steen and Igelösa, XVIVO Perfusion’s heart transplantation competence center in Lund (Sweden) has developed a machine and solutions for heart preservation. The products are developed to increase the availability of donated hearts so that more heart transplants can be performed, and more patients can be given a last chance of a longer life. Clinical multicenter trials are underway in Europe and in the USA and Australia trials in planning phase. The trials form the basis for applications for regulatory approvals for the products in all major markets.

Abdominal

The shortage of transplantable kidneys is great. Studies have shown that transport of kidneys with ongoing perfusion in many cases improves post-transplant results. A high-quality international study has been published in *The Lancet* that shows significant benefits for the recipient when the kidney is transported in an oxygenated solution. This is the technology that is unique to XVIVO. XVIVO’s technology, research and development in kidney perfusion is being used in both preclinical and clinical, investigator-driven studies.

Similarly to other organs, there is a shortage of transplantable livers. By preserving and evaluating the function of the donated liver in an optimized way, potentially more well-functioning organs could be transplanted. XVIVO’s technology, research, and development in warm perfusion of the liver is being used in both preclinical and clinical, investigator-driven studies.

The combination of new perfusion technology and XVIVO’s solutions will be in focus for research and development in kidney and liver transplantation.

Other indications

The company also invests in preclinical and clinical research in xenotransplantation, perfusion of organs remaining in the body, for example, drug administration to isolated organs and priming solutions for heart-lung machines. An extended trial for the company’s priming solution PrimECC® is taking place in Sweden.

Business concept

XVIVO Perfusion’s business concept is to increase the survival rate of patients in need of an organ transplant by providing effective products that increase the availability and survival potential of organs once transplanted.

Vision

The company’s vision is that no one should have to die waiting for a new organ.

Objective

The company’s objective is to establish machine perfusion of organs with STEEN Solution™ and other advanced solutions as the standard treatment in organ transplantation so that more of these lifesaving treatments can be performed.

Strategy

XVIVO Perfusion’s strategy is focused on increasing the number of organs available for transplantation. Through development of products for perfusion of organs and through clinical trials on all major markets in the world, XVIVO Perfusion shows that perfusion of organs gives more organs available for transplantation and thus gives a larger number of patients a life-saving treatment.

OTHER INFORMATION

Organization and personnel

At the end of 2020, the number of employees was 77, of which 31 were women and 46 were men. Of these, 42 people were employed in Sweden and 35 outside Sweden.

Information on transactions with related parties

During the period, one transaction was conducted with a related party. Board member Folke Nilsson has invoiced the company KSEK 69 for consulting services regarding product development.

Risk management

XVIVO Perfusion is constantly working to identify, evaluate, and manage risks in different systems and processes. Risk analyses are performed continually with regard to the company’s normal business activities and also in connection with activities that are outside XVIVO Perfusion’s regular quality system.

The market risks that are determined to have particular importance for the future development of XVIVO Perfusion are access to financial funds and medical resources at clinics around the world. Operational risks primarily comprise risks that limit or prevent XVIVO Perfusion from developing, manufacturing and selling qualitative, effective and safe products. Legal and regulatory risks may arise from changes in legislation and other regulations. Changes in legislation or political decisions may affect the company’s ability to run or develop the business. Included in financial risks are the currency risk for the business.

The most important strategic and operative risks affecting the company are described in the 2019 annual report, which is available on the company website www.xvivoperfusion.com.

Seasonal effects

XVIVO Perfusion's sales are marginally affected by seasonal effects. Mainly in new treatments such as EVLP or warm perfusion in lung transplantation there are slightly less activity during the summer months.

Nomination Committee for the 2021 Annual General Meeting

The following members have been appointed to XVIVO Perfusion's Nomination Committee for the 2021 Annual General Meeting:

Henrik Blomquist, appointed by Bure Equity AB
Martin Lewin, appointed by Eccenovo AB
Caroline Sjösten, appointed by Swedbank Robur Fonder AB
Gösta Johannesson, Chairman of the Board

The appointments have been made in accordance with the instructions regarding principles for the appointment of the company Nomination Committee which were determined at the Annual General Meeting of XVIVO Perfusion AB (publ) on April 27, 2018. The members of the Nomination Committee together represent 30 percent of the votes attached to all voting shares in the company as of August 31, 2020.

Annual General Meeting and Annual Report

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on April 22, 2021 in Gothenburg. Shareholders who wish to have an item considered at the Annual General Meeting can submit a written request to the Board to this effect. Such a request for an item to be considered is to be sent to XVIVO Perfusion AB (publ), Att: Chairman of the Board, Box 53015, 400 14 Gothenburg, and must have been received by the Board no later than seven weeks before the Annual General Meeting, or otherwise in such good time that the matter, where necessary, can be included in the notice to attend the Annual General Meeting.

It is estimated that XVIVO Perfusion's Annual Report for 2020 will be available for download on XVIVO Perfusion's website during the week commencing Monday, March 29.

Events after the end of the reporting period

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

Certification

The Board and the CEO certify that the report gives a true and fair view for the company's and the Group's business activities, financial position and results, and describes the essential risks and uncertainty factors that the company and the companies which are part of the Group faces.

Gothenburg
January 28, 2021

Dag Andersson
CEO

Gösta Johannesson
Chairman of the Board

Camilla Öberg
Board member

Folke Nilsson
Board member

Yvonne Mårtensson
Board member

Lars Henriksson
Board member

Lena Höglund
Board member

This report has not been reviewed by the company's auditors.

Financial reports

XVIVO Perfusion's interim reports are published on the company's website, www.xvivoperfusion.com. The following reports are planned to be submitted:

Interim Report January-March 2021: Wednesday, April 21, 2021
Interim Report January-June 2021: Tuesday, July 13, 2021
Interim Report January-September 2021: Thursday October 28, 2021
Report on Operations 2021: Thursday, January 27, 2022

Conference call

CEO and CFO will present the report in a conference call at 2.00 p.m. CET on Thursday, January 28, 2021.
Telephone UK: +44 333 300 0804, or
USA: +1 631 913 1422. PIN: 37331004#

For further information, please contact

Dag Andersson, CEO, +46 788 21 50,
dag.andersson@xvivoperfusion.com
Kristoffer Nordström, CFO, tel: +46 735 19 21 64,
e-mail: kristoffer.nordstrom@xvivoperfusion.com

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 above on January 28, 2021 at 7.30 am.

This is a translation of the Swedish version of the report. When in doubt, the Swedish wording prevails.

CONDENSED CONSOLIDATED STATEMENT OF NET INCOME

SEKTHOUSANDS	January - December		October - December	
	2020	2019	2020	2019
Net sales	179 861	220 837	60 277	62 416
Cost of goods sold	-46 886	-58 024	-18 920	-16 710
Gross income	132 975	162 813	41 357	45 706
Selling expenses	-59 899	-60 786	-19 229	-18 372
Administrative expenses	-30 342	-24 739	-11 163	-7 152
Research and development costs	-56 178	-62 651	-15 886	-17 964
Other operating revenues and expenses*	-32 231	-10 697	-9 406	-622
Operating income	-45 675	3 940	-14 328	1 596
Financial income and expenses	-11 588	1 350	-11 610	-3 838
Income after financial items	-57 263	5 290	-25 938	-2 242
Taxes	13 528	-351	6 363	340
Net income	-43 735	4 939	-19 575	-1 902
Attributable to				
Parent Company's shareholders	-43 735	4 939	-19 575	-1 902
Earnings per share, SEK	-1,61	0,19	-0,68	-0,07
Earnings per share, SEK**	-1,60	0,18	-0,67	-0,07
Average number of outstanding shares	27 171 352	26 518 546	28 719 136	26 600 496
Average number of outstanding shares**	27 354 518	26 799 996	29 327 136	26 879 496
Number of shares at closing day	28 719 136	26 600 496	28 719 136	26 600 496
Number of shares at closing day**	29 444 136	26 879 496	29 444 136	26 879 496
EBITDA	-15 637	28 800	-6 506	8 479
Amortization	-17 685	-14 539	-5 349	-4 107
Depreciation	-12 353	-10 321	-2 473	-2 776
Operating income	-45 675	3 940	-14 328	1 596

* See note 4 for "Other operation revenues and expenses"

** After dilution. See note 5 for information on warrant programs.

CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME

SEKTHOUSANDS	January - December		October - December	
	2020	2019	2020	2019
Net income	-43 735	4 939	-19 575	-1 902
Other comprehensive income				
<i>Items that may be reclassified to the income statement</i>				
Exchange rate differences	-16 410	3 721	-13 179	-3 691
Tax attributable to items that have been transferred, or can be transferred to net income	0	-514	-153	343
Total other comprehensive income, net after tax	-16 410	3 207	-13 332	-3 348
Total comprehensive income	-60 145	8 146	-32 907	-5 250
Attributable to				
Parent Company's shareholders	-60 145	8 146	-32 907	-5 250

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK THOUSANDS	Dec 31, 2020	Dec 31, 2019
ASSETS		
Goodwill	223 938	65 773
Capitalized development expenditure	393 969	266 517
Other intangible fixed assets	6 750	6 219
Fixed assets	21 334	23 554
Financial assets	41 088	12 539
Total non-current assets	687 079	374 602
Inventories	59 351	43 871
Current receivables	49 643	56 068
Liquid funds	354 236	159 946
Total current assets	463 230	259 885
Total assets	1 150 309	634 487
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity, attributable to the Parent Company's shareholders	1 008 461	577 521
Long-term interest-bearing leases	1 474	2 154
Long-term non-interest-bearing liabilities	66 314	2 213
Short-term interest-bearing leases	5 738	3 396
Short-term non-interest-bearing liabilities	68 322	49 203
Total shareholders' equity and liabilities	1 150 309	634 487

CONSOLIDATED KEY RATIOS

	January - December		October - December	
	2020	2019	2020	2019
Gross margin non-Durable goods, %	77	77	72	77
Gross margin, %	74	74	69	73
EBITDA, %	-9	13	-11	14
Operating margin, %	-25	2	-24	3
Net margin, %	-24	2	-32	-3
Equity/assets ratio, %	88	91	88	91
Income per share, SEK	-1,61	0,19	-0,68	-0,07
Shareholders' equity per share, SEK	35,11	21,71	35,11	21,71
Share price on closing day, SEK	314,00	170,00	314,00	170,00

See page 18-19 for key ratios definition and reconciliation of alternative key figures.

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEKTHOUSANDS	January - December		October - December	
	2020	2019	2020	2019
Income after financial items	-57 263	5 290	-25 938	-2 241
Adjustment for items not affecting cash flow	49 355	28 862	22 720	12 722
Paid taxes	142	-2 945	1 247	-182
Change in inventories	-14 155	-8 478	1 482	1 892
Change in trade receivables	20 584	-542	8 051	-6 292
Change in trade payables	-10 929	7 318	-29 561	-13 117
Cash flow from operating activities	-12 266	29 505	-21 999	-7 218
Cash flow from investing activities	-266 532	-83 844	-222 189	-26 341
Cash flow from financing activities	482 768	25 551	-1 710	-686
Cash flow for the period	203 970	-28 788	-245 898	-34 245
Liquid funds at beginning of period	159 946	187 064	608 374	197 643
Exchange rate difference in liquid funds	-9 680	1 670	-8 240	-3 452
Liquid funds at end of period	354 236	159 946	354 236	159 946

CONSOLIDATED CHANGES IN SHAREHOLDERS EQUITY

SEKTHOUSANDS	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 1 January, 2019	675	486 860	13 020	39 922	540 477
Total comprehensive income Jan - Dec, 2019			3 207	4 939	8 146
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	5	27 296			27 301
Share warrant program		1 597			1 597
Shareholders' equity as of 31 december, 2019	680	515 753	16 227	44 861	577 521
Total comprehensive income January - Dec, 2020			-16 410	-43 735	-60 145
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	54	489 640			489 694
Share warrant program		1 391			1 391
Shareholders' equity as of 31 December, 2020	734	1 006 784	-183	1 126	1 008 461

CONDENSED CONSOLIDATED STATEMENT OF NET INCOME PER QUARTER

SEKTHOUSANDS	Oct - Dec 2020	Jul - Sep 2020	Apr - Jun 2020	Jan - Mar 2020	Oct - Dec 2019	Jul - Sep 2019	Apr - Jun 2019	Jan - Mar 2019
Net sales	60 277	42 736	30 393	46 455	62 416	54 334	56 437	47 650
Cost of goods sold	-18 920	-9 602	-7 291	-11 073	-16 710	-15 791	-14 789	-10 734
Gross income	41 357	33 134	23 102	35 382	45 706	38 543	41 648	36 916
Selling expenses	-19 229	-13 470	-12 360	-14 840	-18 372	-14 376	-15 957	-12 081
Administrative expenses	-11 163	-8 462	-5 069	-5 648	-7 152	-6 029	-6 148	-5 410
Research and development costs	-15 886	-11 233	-12 186	-16 873	-17 964	-16 827	-12 898	-14 962
Other operating revenues and expenses*	-9 406	-18 631	-6 196	2 002	-622	966	-4 716	-6 325
Operating income	-14 328	-18 661	-12 709	23	1 596	2 277	1 929	-1 862
Financial income and expenses	-11 610	-481	-6 047	6 550	-3 838	3 210	527	1 451
Income after financial items	-25 938	-19 142	-18 756	6 573	-2 242	5 487	2 456	-411
Taxes	6 363	4 457	2 738	-30	340	-558	-229	96
Net income	-19 575	-14 685	-16 018	6 543	-1 902	4 929	2 227	-315
Attributable to								
Parent Company's shareholders	-19 575	-14 685	-16 018	6 543	-1 902	4 929	2 227	-315
Earnings per share, SEK	-0,68	-0,51	-0,60	0,25	-0,07	0,19	0,08	-0,01
Earnings per share, SEK**	-0,67	-0,51	-0,60	0,25	-0,07	0,18	0,08	-0,01
Average number of outstanding shares	28 719 136	28 601 434	26 600 496	26 600 496	26 600 496	26 600 496	26 532 296	26 402 496
Average number of outstanding shares**	29 327 136	28 975 434	26 600 496	26 600 496	26 879 496	26 879 496	26 879 496	26 720 496
Number of shares at closing day	28 719 136	28 719 136	26 600 496	26 600 496	26 600 496	26 600 496	26 600 496	26 402 496
Number of shares at closing day**	29 444 136	29 093 136	26 600 496	26 600 496	26 879 496	26 879 496	26 879 496	26 879 496
EBITDA	-6 506	-11 229	-5 452	7 550	8 479	9 025	8 055	3 241
Amortization	-5 349	-4 114	-4 107	-4 115	-4 107	-4 099	-3 618	-2 715
Depreciation	-2 473	-3 318	-3 150	-3 412	-2 776	-2 649	-2 508	-2 388
Operating income	-14 328	-18 661	-12 709	23	1 596	2 277	1 929	-1 862

* See note 4 for "Other operating revenues and expenses"

** After dilution. See note 5 for information on warrant programs.

CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME PER QUARTER

SEKTHOUSANDS	Oct - Dec 2020	Jul - Sep 2020	Apr - Jun 2020	Jan - Mar 2020	Oct - Dec 2019	Jul - Sep 2019	Apr - Jun 2019	Jan - Mar 2019
Net income	-19 575	-14 685	-16 018	6 543	-1 902	4 929	2 227	-315
Other comprehensive income								
<i>Items that may be reclassified to the income statement</i>								
Exchange rate differences	-13 179	-3 654	-5 226	5 649	-3 691	4 531	30	2 851
Tax attributable to items that have been transferred, or can be transferred to net income	-153	299	319	-465	343	-487	-20	-350
Total other comprehensive income, net after tax	-13 332	-3 355	-4 907	5 184	-3 348	4 044	10	2 501
Total comprehensive income	-32 907	-18 040	-20 925	11 727	-5 250	8 973	2 237	2 186
Attributable to								
Parent Company's shareholders	-32 907	-18 040	-20 925	11 727	-5 250	8 973	2 237	2 186

CONDENSED INCOME STATEMENT FOR THE PARENT COMPANY

SEK THOUSANDS	January - December		October - December	
	2020	2019	2020	2019
Net sales	134 122	169 608	37 644	47 737
Cost of goods sold	-36 107	-50 677	-11 076	-17 514
Gross income	98 015	118 931	26 568	30 223
Selling expenses	-36 675	-36 502	-11 893	-9 915
Administrative expenses	-27 602	-18 485	-10 436	-6 596
Research and development costs	-65 268	-65 937	-18 401	-16 291
Other operating revenues and expenses	-10 074	-181	2 992	2 980
Operating income	-41 604	-2 174	-11 170	401
Financial income and expenses	-10 609	4 774	-10 456	-5 066
Income after financial items	-52 213	2 600	-21 626	-4 665
Year end dispositions	4 200	-2 300	4 200	-
Taxes	9 577	-299	3 380	83
Net income	-38 436	1	-14 046	-4 582

The Parent Company has no items to report as other comprehensive income, therefore a statement of comprehensive income is not presented.
Depreciation and amortization has reduced income for the period by SEK 19 907 (17 832) thousand, of which SEK 4 929 (4 991) thousand for the quarter.

CONDENSED BALANCE SHEET FOR THE PARENT COMPANY

SEK THOUSANDS	Dec 31, 2020	Dec 31, 2019
ASSETS		
Intangible fixed assets	245 777	206 205
Fixed assets	5 902	7 924
Financial assets	453 598	194 166
Total non-current assets	705 277	408 295
Inventories	16 561	15 070
Current receivables	25 602	34 352
Cash and bank	333 318	150 362
Total current assets	375 481	199 784
Total assets	1 080 758	608 079
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity	1 000 817	548 150
Untaxed reserves	0	4 200
Provisions	1 311	6 734
Provisions	41 392	0
Short-term non-interest-bearing liabilities	37 238	48 995
Total shareholders' equity and liabilities	1 080 758	608 079

SUPPLEMENTARY NOTES

Disclosures in accordance with IAS 34.16A occur in the financial statements and the related notes, as well as elsewhere in parts of the interim report.

Note 1. Accounting principles

For the Group, the 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 for the Group and the parent company correspond, unless otherwise stated below, with the accounting policies used for the preparation of the latest annual report.

Note 2. Financial instruments

The Group's financial assets and liabilities valued at acquisition value amount to SEK 404 (216) million and SEK 68 (49) million respectively. Fair value of the Group's financial assets and liabilities is assessed to correspond to the book value.

Note 3. Financial data per segment, Group

Net sales and costs of goods sold are divided into the segments durable goods and non-durable goods. The company's operations are followed up in two business areas; Thoracic, which includes sales of products in lung and heart

transplantation, and Abdominal, which includes sales of products in liver and kidney transplantation.

TOTAL

SEK Thousands	January - December						October - December					
	Net sales of non-Durable goods		Durable goods		Total consolidated		Net sales of non-Durable goods		Durable goods		Total consolidated	
	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019
Net sales	169 425	206 857	10 436	13 980	179 861	220 837	54 927	59 401	5 350	3 015	60 277	62 416
Cost of goods sold	-38 980	-47 439	-7 906	-10 585	-46 886	-58 024	-15 143	-13 771	-3 777	-2 939	-18 920	-16 710
Gross income	130 445	159 418	2 530	3 395	132 975	162 813	39 784	45 630	1 573	76	41 357	45 706
(%)	77%	77%	24%	24%	74%	74%	72%	77%	29%	3%	69%	73%

THORAX

SEK Thousands	January - December						October - December					
	Net sales of non-Durable goods		Durable goods		Total consolidated		Net sales of non-Durable goods		Durable goods		Total consolidated	
	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019
Net sales	155 572	206 857	7 720	13 980	163 292	220 837	41 074	59 401	2 634	3 015	43 708	62 416
Cost of goods sold	-32 048	-47 439	-6 291	-10 585	-38 339	-58 024	-8 211	-13 771	-2 162	-2 939	-10 373	-16 710
Gross income	123 524	159 418	1 429	3 395	124 953	162 813	32 863	45 630	472	76	33 335	45 706
(%)	79%	77%	19%	24%	77%	74%	80%	77%	18%	3%	76%	73%

ABDOMINAL

SEK Thousands	January - December						October - December					
	Net sales of non-Durable goods		Durable goods		Total consolidated		Net sales of non-Durable goods		Durable goods		Total consolidated	
	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019
Net sales	13 853	0	2 716	0	16 569	0	13 853	0	2 716	0	16 569	0
Cost of goods sold	-6 932	0	-1 615	0	-8 547	0	-6 932	0	-1 615	0	-8 547	0
Gross income	6 921	0	1 101	0	8 022	0	6 921	0	1 101	0	8 022	0
(%)	50%	-	41%	-	48%	-	50%	-	41%	-	48%	-

Note 4. Other operating revenues and expenses

TSEK	Oct - Dec 2020	Jul - Sep 2020	Apr - Jun 2020	Jan-Mar 2020	Oct - Dec 2019	Jul - Sep 2019	Apr - Jun 2019	Jan-Mar 2019
Cost of cash-based incentive program for employees outside Sweden	-8 332	-12 469	-	2 541	237	2 253	-4 000	-5 536
Cost of reorganization	-	-5 375	-4 498	-	-	-	-	-
Other	-1 074	-786	-1 698	-539	-859	-1 287	-716	-789
Total	-9 406	-18 630	-6 196	2 002	-622	966	-4 716	-6 325

Note 5. Share warrant programs for employees

In total there are 725,000 outstanding warrants in two programs.

The Annual General Meeting of 2019 resolved to issue a maximum of 351,000 warrants (series 2019/2021), with the right to subscribe a maximum of 351,000 new shares to employees of the XVIVO Perfusion Group. Of these warrants, all 351,000 have been subscribed by employees. Warrant program series 2019/2021 gives the warrant holder the right to subscribe for a new share in May 2021 at a price of SEK 278.91.

The Annual General Meeting of 2020 resolved to issue a maximum of 408,000 warrants (2020/2022 series) with the right to subscribe a maximum of 408,000 new shares to employees of the XVIVO Perfusion Group. Of these warrants, 374,000 have been subscribed for by employees. Warrant program 2020/2022 gives the warrant holder the right to subscribe for a new share in May 2022 at a price of SEK 205.88.

During the period January-December 2020, both the average share price for the period and the closing price at period end exceeded the exercise price of both warrant program series 2019/2021 and warrant program series 2020/2022, whereby the warrant programs at strike are expected to result in a total dilution effect for existing shares of approximately 2.5 percent.

The Annual General Meeting in 2019 and 2020 decided to approve a cash-based incentive program for the Group's employees in countries outside Sweden, as these employees are not entitled to participate in the Swedish warrant programs. The cash-based programs should, as far as practically possible, be designed to correspond to the Swedish warrant programs but have a limit for maximum outcome. The cost of these cash-based incentive programs is recognized in the periods when XVIVO's share price exceeds the exercise price for each Swedish warrant program. The cost is reported under the item "Other operating income and expenses" and is described in Note 4.

Not 6. Acquisition of business

On October 1, XVIVO acquired 100 percent of the shares in the Dutch medical technology company Organ Assist B.V. The acquisition takes place at a cash purchase price of up to EUR 24 million, with an initial payment of EUR 20 million and potential additional purchase prices of a total of up to EUR 4 million. The additional purchase price is divided into two milestone payments, of a maximum of EUR 2 million each, based on sales targets for 2021 and regulatory approval in the USA for Organ Assist's kidney device. Costs attributable to the acquisition amounted to SEK 2.7 million and were charged to Administrative expenses in the consolidated income statement during the year.

Organ Assist focuses mainly on developing machines and consumables for perfusion of the liver and kidneys. Through the acquisition, XVIVO will be the first company for the preservation and evaluation of organs in the world to actively conduct activities that include all major organs, which accelerates the company's strategy to become a global supplier of solutions and systems for all major organs. The companies' synergies enable greater market opportunities for XVIVO's and Organ Assist's product portfolios by integrating XVIVO's unique and patented STEEN Solution™ technology with Organ Assist's kidney and liver devices, as well as by utilizing XVIVO's international market presence. The combined offering expands XVIVO's addressable market to approximately 98 percent of the organ transplant market with the goal of positioning the company as the first choice for all multi-organ clinics.

The acquisition date is October 1 and income and cash flow are not included in the consolidated financial statements until this date. During the time after the acquisition, Organ Assist contributed with SEK 16.6 million to the net sales of the group and SEK 1.1 million to the net result. If the acquisition had taken place on January 1st 2020, the entity would have contributed with net sales of SEK 41.8 million and a net result of -3.1 million.

The acquisition analysis was preliminary in Q3 but has now been finalized. The table below shows the final acquisition analysis.

Purchase price	Fair Value (TSEK)
Paid purchase price as at October 1, 2020	201 320
Conditional additional purchase price	41 973
Total	243 293
Acquired assets	
Intangible assets	87 372
Tangible fixed assets	1 475
Inventories	14 360
Accounts receivable and other receivables	18 155
Liquid funds	1
Deferred tax	-12 706
Accounts payable and other liabilities	-31 257
Fair value of acquired net assets	77 400
Goodwill	165 893
Total	243 293

Impact on the Group's cash flow

Purchase price, initial payment in cash	201 320
Less: Cash and cash equivalents in acquired company	1
Impact on the Group's cash and cash equivalents	201 319

Goodwill primarily consists of synergy effects that do not meet the requirements for accounting as intangible assets at the time of the acquisition. Primary synergies are potentially increased sales values per client as well as increased sales potential for new clients, which can be achieved through XVIVOS knowledge and experience within global marketing and regulatory issues. Synergies which could contribute to future net sales is also to be found within research and development.

RECONCILIATION OF KPI NUMBERS

This report includes certain key ratios not defined in IFRS, but they are included in the report as company management considers that this information makes it easier for investors to analyze the Group's financial performance and position. Investors should regard these alternative key ratios as complementing rather than replacing financial information in accordance with IFRS.

EBITDA

SEK THOUSANDS	Jan - Dec		Oct - Dec	
	2020	2019	2020	2019
Operating income	-45 675	3 940	-14 328	1 596
Amortization	17 685	14 539	5 349	4 107
Depreciation	12 353	10 321	2 473	2 776
EBITDA	-15 637	28 800	-6 506	8 479

Gross margin

SEK THOUSANDS	Jan - Dec		Oct - Dec	
	2020	2019	2020	2019
Operating income				
Net sales	179 861	220 837	60 277	62 416
Operating expenses				
Cost of goods sold	-46 886	-58 024	-18 920	-16 710
Gross income	132 975	162 813	41 357	45 706
Gross margin %	74	74	69	73

Gross margin non-Durable goods

SEK THOUSANDS	Jan - Dec		Oct - Dec	
	2020	2019	2020	2019
Operating income				
Net sales of non-Durable goods	169 425	206 857	54 927	59 401
Operating expenses				
Cost of non-Durable goods sold	-38 980	-47 439	-15 143	-13 771
Gross income, non-Durable goods	130 445	159 418	39 784	45 630
Gross margin, non-Durable goods %	77	77	72	77

To calculate the gross profit margin, gross profit is first calculated by subtracting the cost of goods for resale from net sales. Gross profit is then divided by net sales to obtain the performance measure of "gross profit margin." Gross profit margin states the percentage of net sales that are converted into profit after cost of goods sold, and is impacted by such factors as pricing, the cost of raw materials and manufacturing, inventory impairment and trends in exchange rates.

Equity/assets ratio

SEK THOUSANDS	Dec 31, 2020	Dec 31, 2019
Shareholders' equity	1 008 461	577 521
Total assets	1 150 309	634 487
Equity/assets ratio %	88	91

Equity consists of share capital, other contributed capital, reserves and retained earnings, including the Group's profit for the year and non-controlling interests. Equity/assets ratio is calculated by dividing equity by total assets and is thus a measure of the percentage of assets that are financed by equity.

KPI DEFINITIONS

KEY RATIO	DEFINITION	JUSTIFICATION TO USE OF KEY RATIO
Gross margin non-Durable goods, %	Gross income segment non-Durable goods as a percentage of the net sales of segment non-Durable goods.	The company believes that the key ratio provides an in-depth understanding of the company's profitability for operations for non-Durable goods. Since the pricing strategy for durable goods differs from the pricing strategy from all other operations, the gross margin is excluded separately from durable goods.
Gross margin, %	Gross income as a percentage of the net sales for the period.	The company believes that the key ratio provides an in-depth understanding of the company's profitability.
EBITDA margin, %	Operating income before depreciation and amortization as a percentage of net sales for the period.	The company believes that the key ratio provides an in-depth understanding of the company's profitability.
Operating margin, %	Operating income as a percentage of net sales for the period.	The company believes that the key ratio provides an in-depth understanding of the company's profitability.
Net margin, %	Income for the period as a percentage of 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 and non-controlling interests as a percentage of total assets.	The company believes that the equity to asset ratio provides 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 at closing day.	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 in relation to the average number of outstanding shares for the period.	The key ratio has been included to give investors an overview of how the company's earnings per share has evolved.
Earnings per share after dilution, SEK	Income for the period in relation to the average number of outstanding shares after dilution for the period.	The key ratio has been included to give investors an overview of how the company's equity per share after dilution has evolved.

GLOSSARY

The following explanations are intended to help the reader understand certain specific terms and expressions in XVIVO Perfusion's reports:

Clinical study/trial

An investigation in healthy or sick people to study the effect of a drug or method of treatment.

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. "Opposite" of in vivo.

EVLP or Ex Vivo Lung Perfusion

Perfusion of a lung outside the body. The procedure is normally done to evaluate a lung before transplantation.

FDA or US Food and Drug Administration

The FDA is the USA's 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 American market.

HDE or Humanitarian Device Exemption

A humanitarian device exemption (HDE) application can be submitted to the FDA for a 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 the supply of oxygen and necessary nutrients during transport to the recipient.

In vivo

Biological processes in living cells and tissues when they are in their natural place in intact organisms.

Machine perfusion

New technology that improves preservation and evaluation of organs, which means more organs can be used for transplants. Within the business area Thoracic this includes STEEN Solution™, XPS™, LST™, Lung Assist and Heart Assist as well as other products and services related to the use of those products. Within the business area Abdominal this includes Kidney Assist Transport, Kidney Assist and Liver Assist as well as other products and services related to the use of those machines.

Medical device

Comprises devices used to diagnose a disease or treat a disease and as rehabilitation.

Obstructive lung disease

Disease where there is airway obstruction.

OPO or Organ Procurement Organization

In the United States, an organ procurement organization (OPO) is a non-profit organization that is responsible for the evaluation and procurement of deceased-donor organs for organ transplantation. There are approximately 58 such organizations in the United States.

Other Sales

In terms of product category, Other sales refers to income relating to freight, service and training.

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 Class III medical devices. Class III devices support or sustain human life, are of substantial importance in preventing impairment of human health, or potentially present an unreasonable risk of illness or injury.

Preclinical study

Research performed before a drug or method of treatment is sufficiently documented to be studied in humans, for example the testing of substances in tissue samples and subsequent testing in experimental animals.

Preservation

Storage and maintenance of an organ outside the body before transplantation.

Reimbursement

Reimbursement is relevant within the health insurance system for healthcare providers to be paid 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 kept cold during transport and before transplantation. Within the business area Thoracic this includes Perfadex® Plus as well as other products and services related to the use of that product.

CURRENT R&D PORTFOLIO

PROJECT	DESCRIPTION	STATUS
DEVELOPMENT PROJECTS		
Heart transplantation 	<p>What primarily limits how many people can receive a heart transplant today is the number of available, and using today's technology, usable donated organs, in combination with the time that a donated heart can be outside the body. XVIVO is working in collaboration with Professor Stig Steen to develop a holistic solution consisting of fluids and machinery that better preserve the function of the donated heart during transport and thus can contribute to improved results after heart transplantation.</p>	<p>The company is developing a program with clinical multicenter studies. These studies will form the basis for the application for regulatory approval of the products in all the major markets in the world. In Europe, the first patients have been included in the study that, in total, will include 202 patients in nine centers in seven countries. Patients are selected by lottery to be transplanted either with donated hearts transported by XVIVO's method or preserved using the traditional icebox method. A similar multicenter study is in the planning phase in the US as well, where the company has received a so-called "breakthrough device designation" and the conditions for starting the study are under discussion with the FDA. In addition to the studies that XVIVO conducts, the Swedish investigator-driven study that uses XVIVO's technology continues to include patients. A supplementary investigator-driven study is also being launched in Australia.</p>
PrimECC 	<p>PrimECC® is a fluid that has been developed in collaboration with Professor Stig Steen in Lund and is intended for use in a heart-lung machine. This machine completely assumes control of the function of the heart and lungs during the several hundred thousand heart operations that are performed annually. Before the heart-lung machine is connected to a patient, the machine must be filled with fluid, which today usually is a simple saline solution. The hope is that the use of PrimECC® for this purpose will reduce side effects related to the use of the heart-lung machine by protecting the body's organs.</p>	<p>XVIVO Perfusion has patents for PrimECC® in the important markets of the US, the EU, China, and Japan, and the product has already been granted a CE mark. In 2016 and 2017, a randomized clinical study of 80 patients was conducted which indicated positive effects of PrimECC®. During the fourth quarter, Sahlgrenska University Hospital, continued to include patients in the new, extended study in Sweden. Inclusion rates have been affected by the fact that the number of heart surgeries has decreased as a result of the Covid-19 pandemic. The company is waiting with the product launch until the study results have been analyzed.</p>
Kidney transplantation 	<p>Similarly to other organs, there is a lack of transplantable kidneys. Studies have shown that transport of kidneys with ongoing perfusion in many cases improves post-transplant results. Evaluation of the kidney's function with warm perfusion is under development. The optimal method for transporting donated kidneys is being studied in several ongoing, international studies.</p>	<p>In the fourth quarter, The Lancet published a high-quality international study. The study shows significant benefits for the recipient when the kidney is transported in an oxygenated solution. This is the technology that is unique to XVIVO. In connection with XVIVO's acquisition of Organ Assist, technology, research and development in kidney perfusion were added in both preclinical and clinical, investigator-driven studies. The combination of new perfusion technology and XVIVO's solutions will be in focus for future research in the kidney transplantation.</p>
Liver transplantation 	<p>Similarly to other organs, there is a lack of transplantable livers. By preserving and evaluating the function of the donated liver in an optimized way, potentially more well-functioning organs could be transplanted. Studies indicate that perfusion of the liver before transplantation reduces the risk of complications.</p>	<p>The company's acquisition of Organ Assist brought technology, research, and development in warm perfusion of the liver in both preclinical and clinical, investigator-driven studies. Several of these clinical trials are in the final stages. The combination of new perfusion technology and XVIVO's solutions will be in focus for future research in liver transplantation.</p>

RESEARCH PROJECTS

Xeno-transplantation 	<p>Xenotransplantation is based on the use of non-human organs in transplantation. The method is currently in the research stage for several organs.</p>	<p>XVIVO's technology for preserving heart function is currently, continuously, used by two world-leading research groups and has been crucial for successful results when genetically modified hearts from pigs are transplanted into primates.</p>
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