

INTERIM REPORT JANUARY-JUNE 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. Currently, the company's product, Perfadex® Plus, has a market share of more than 90 percent in the traditional preservation of lungs for transplantation. The company's products for warm perfusion, XPS $^{\text{TM}}$ and STEEN Solution $^{\text{TM}}$, have regulatory approval in all major markets, and are the only products to date to have received regulatory approval from the FDA for warm perfusion of marginal lungs. XVIVO Perfusion also develops the next generation of heart storage products pending transplantation, which involves storing and transporting hearts from a donor in an optimized way, through non-ischemic heart preservation.

XVIVO Perfusion employs around 60 people at its headquarters in Gothenburg, Sweden, its office in Lund, Sweden, 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.



IN THE STARTING BLOCKS FOR HEART PRESERVATION AND PRIMECC TRIAL START

SECOND QUARTER 2020 (APRIL-JUNE)

- Net sales of non-durable goods* in the quarter amounted to SEK 28.0 (50.5) million, corresponding to a decrease of 44 percent in SEK and 46 percent in local currency. Total net sales (incl. durable goods) in the quarter amounted to SEK 30.4 (56.4) million, corresponding to a decrease of 46 percent in SEK and 47 percent in local currency. The Covid-19 pandemic has had a large impact on the sales and product mix during the quarter. The Covid-19 pandemic has resulted in a decrease of lung transplants since intensive Care units have been concentrating on managing the pressure from Covid-19 patients requiring intensive care treatment. In the important markets, the company has seen some recovery in the US as of May and in Europe as of June. Since transplantation is a life-sustaining treatment and transplants are prioritized by health authorities around the world. Therefore, the company believes that the long-term effect on demand for transplant products will be unchanged.
- Warm perfusion** sales accounted for 37 (45) percent of the total sales of non-durable goods.
- Operating income before depreciation and amortization, EBITDA, amounted to SEK -5.5 (8.1) million, corresponding to an EBITDA margin of -18 percent (14). EBITDA during the quarter was affected by costs from organizational

- changes of SEK -4.5 million. Adjusted for this cost, EBITDA for the quarter amounted to SEK -1.0 (12.1) million, corresponding to an EBITDA margin of -3 percent (21).
- Operating income amounted to SEK -12.7 (1.9) million, after amortization and depreciation of SEK 7.3 (6.1) million. Adjusted for the above costs, operating income amounted to SEK -8.2 (5.9) million.
- Net income amounted to SEK -16.0 (2.2) million, resulting in earnings per share of SEK -0.60 (0.08).
- Cash flow from operating activities during the quarter amounted to SEK 2.4 (21.0) million. Cash flow from investing activities amounted to SEK -13.9 (-27.8) million.
- Dag Andersson was appointed as a new President and CEO. XVIVO Perfusion's founder and former CEO, Magnus Nilsson, remains time as Senior Advisor to primarily work with R&D.
- Anne-Li Sigvardsson, MSc has been appointed Chief Intellectual Property Officer. Andreas Wallinder, MD, PhD has been appointed Chief Medical Officer.
- During the quarter, the scientific journal Nature Communications published an article describing the use of XVIVO Perfusions heart preservation technology and the study results that proofs that the method is safe.
- The University Hospital AKH in Vienna, Austria, which is one of the three largest lung transplant clinics in Europe, has purchased an XPS™.

THE PERIOD 2020 (JANUARY - JUNE)

- Net sales of non-durable goods* in the period amounted to SEK 72.2 (97.3) million, corresponding to a decrease of 26 percent in SEK and 28 percent in local currency. Total net sales (incl. durable goods) in the period amounted to SEK 76.9 (104.1) million, corresponding to a decrease of 26 percent in SEK and 28 percent in local currency. The Covid-19 pandemic has had a large impact on the sales and product mix during the period.
- Sales from warm perfusion** represented 31 percent (44) of sales of non-durable goods.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 2.1 (11.3) million, corresponding to an EBITDA margin of 3 percent (11).EBITDA has been affected by costs from organizational changes of SEK -4.5 million, while the resolution of cost provisions for share-based bonus programs for employees outside Sweden contributed positively with SEK 2.5 million. EBITDA adjusted for these items amounted to SEK 4.1 (20.8) million, corresponding to an EBITDA margin of 5

percent (20).

- Operating income amounted to SEK -12.7 (0.1) million, after amortization and depreciation of SEK 14.8 (11.2) million. Adjusted for the above items, operating income amounted to SEK -10.7 (9.6) million.
- Net income amounted to SEK -9.5 (1.9) million, resulting in earnings per share of SEK -0.36 (0.07).
- Cash flow from operating activities for the period amounted to SEK 11.6 (22.1) million. Cash flow from investing activities amounted to SEK -29.7 (-39.5) million.
- The advanced and more user-friendly Perfadex® Plus with Click Port has been launched worldwide.
- For the first time, an XPS [™] has been delivered to a pediatric hospital in Rome, Italy. At the end of the period, 53 clinics had access to XPS [™] or LS [™].
- The company's studies for PrimECC® and heart preservation before transplantation, are ready to include the first patients in Europe. These two studies have not been able to start during the period due to clinics in Europe temporarily pausing all clinical trials during the Covid-19 pandemic.

MILESTONES PASSED DURING THE QUARTER

Magnus Nilsson handed over the baton to Dag Andersson as President and CEO

The cardiac preservation study from Lund was published in Nature Communications

CEO'S COMMENTS



Sales in the second quarter were, as previously adviced, affected by the Covid-19 pandemic because intensive care around the world has focused on the treatment of Covid-19 patients. Total sales for the quarter amounted to SEK 30.4 million, compared with SEK 56.4 million for the same period last year.

In addition, the company's product mix was affected during the quarter as sales of warm perfusion products decreased to a greater extent than sales of cold perfusion products. Given this, I am glad to see that XVIVO delivered a positive operating cash flow during the quarter of SEK 2.4 million. Since transplantation is a life-sustaining treatment and transplants are prioritized by health authorities worldwide, our assessment is that the long-term impact on demand for transplant products will remain unchanged. In order to adapt the cost situation to a temporarily reduced demand, XVIVO carries out a cost reduction program.

The Covid-19 pandemic also impacted the starting date for the clinical studies in the field of heart transplantation and PrimECC® that were due to start during the first quarter. At present, it looks as if these will start during the third quarter. The number of transplantations recovered somewhat during the latter part of the second quarter as the pressure on intensive care lifted in above all North America and Europe. A sign of this was that one of the world's largest clinics (AKH in Vienna) bought an XPS machine in order to enable evaluation of lungs using our fluids. The clinic has set up an XPS programme in record time and performed evaluations of lungs using our machine and our solutions. AKH in Vienna is a prominent clinic that during the quarter also performed a transplantation in a patient whose lungs had been destroyed by a Covid-19 infection.

Important progress was made during the quarter in the future growth area of heart transplantation. An article was published in Nature Communications. This article describes

the results for six patients who received transplants after donated hearts were preserved during transportation using the new technology. These six patients were compared with 25 patients where donated hearts were preserved during transportation using the traditional method (traditional ice box). After six months all patients (100 percent) who had received transplants using the new technology were alive and without serious complications related to heart function or rejection. The corresponding outcome in the control group of 25 patients was 72 percent. We are delighted to note that the results from the study show that our method is safe and functional for clinical use. The medical authorities in Belgium, France and Germany have already approved our European study and the study can thus start in the third guarter. As XVIVO's patent application for heart preservation fluid has already been approved in both the US and Europe, the company will focus with full force on the clinical studies in these two regions.

I am impressed by the high level of competence and all the committed employees that I have met here at XVIVO during my initial period as the company's CEO. To support clinical development, a Head of IP and Scientific Affairs and a Chief Medical Officer have been appointed. These two positions will strengthen the company's future competitiveness and enable effective clinical studies that will take the company's development projects through the regulatory phase to commercialization. Furthermore, during autumn the organization will be strengthened by a Head of Commercial manager and a Head of R&D so as to further strengthen the offering to customers by constantly improving our fluids and machines and optimizing time to market for these improvements.

I look forward to the second half of 2020 with confidence and to XVIVO continuing to deliver on the objective of leading the customer-related development of innovative fluids and machines so as to give more patients the opportunity to receive an organ transplant.

Dag Andersson CEO

CONFERENCE CALL

CEO Dag Andersson will present the report in a conference call at 2 p.m. CET on Friday, July 10, 2020. Telephone UK: +44 333 300 0804 or USA: +1 631 913 1422. PIN: 84626045#

SECOND QUARTER 2020 (APRIL - JUNE)

Net Sales

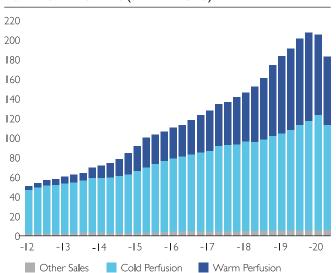
The Covid-19 pandemic has had a large impact on the sales and product mix during the quarter. In the important markets, the company has seen some recovery in the US from May and

NET SALES
ROLLING 12 MONTHS (SEK MILLIONS)*



in Europe from June. 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. Total net sales in the quarter amounted to SEK 30.4 (56.4) million, corresponding to a decrease of 46 percent in SEK and 47 percent in local currency. Net sales of non-durable goods* in the quarter amounted to SEK 28.0 (50.5) million, corresponding to a decrease of 44 percent in SEK and 46 percent in local currency.

NET SALES EXCL. DURABLE GOODS ROLLING 12-MONTHS (SEK MILLIONS)



COMPILATION OF NET SALES AND EBITDA

		January - June		April – June		
SEKTHOUSANDS	2020	2019	2020	2019	2019	
Net Sales non-Durable Goods	72 189	97 319	28 003	50 530	206 857	
Net Sales Durable Goods	4 659	6 768	2 390	5 907	13 980	
Net Sales Total	76 848	104 087	30 393	56 437	220 837	
Cost of Goods non-Durable Goods	-14415	-21 991	-5 316	-11 462	-47 439	
Cost of Goods Durable goods	-3 949	-3 532	-1 975	-3 326	-10 585	
Cost of Goods Total	-18 364	-25 523	-7 29 I	-14 789	-58 024	
Gross income non-Durable Goods	57 774	75 328	22 687	39 068	159 418	
Gross margin non-Durable Goods, %	80%	77%	81%	77%	77%	
Gross income Durable Goods	710	3 236	415	2 581	3 395	
Gross income Total	58 484	78 564	23 102	41 648	162 813	
Gross margin Total, %	76%	75%	76%	74%	74%	
Selling expenses	-27 200	-28 038	-12 360	-15 957	-60 786	
Administrative expenses	-10717	-11 558	-5 069	-6 148	-24 739	
Research and development costs	-29 059	-27 860	-12 186	-12 898	-62 65	
Other operating revenues and expenses**	-4 194	-11041	-6 196	-4716	-10 697	
Operating Income	-12 686	67	-12 709	I 929	3 940	
Deprecation of cost of goods sold	-431	-399	-216	-82	-815	
Deprecation of administrative expenses	-1 520	-957	-757	-500	-2216	
Amortization of research and development expenses	-10 025	-7 234	-4 993	-4 199	-16 624	
Deprecation of other operative expenses	-2 808	-2 639	-1 291	-1 345	-5 205	
EBITDA	2 098	11 296	-5 452	8 055	28 800	
EBITDA,%	3%	11%	-18%	14%	13%	

^{*} See note 2 for revenue per segment. ** See note 4 for "Other operating revenues and expenses"

Total sales from products for warm perfusion (STEEN Solution™, XPS™, LS™, and products and services related to the use of the XPS™ and LS™) accounted for 42 percent (50) of the total sales. Warm perfusion sales from non-durable goods (STEEN Solution™, products and services related to the use of the XPS™ and LS™) accounted for 37 percent (45) of the total sales of non-durable goods. Sales of warm perfusion products were affected during the quarter, partly due to fewer EVLP:s being performed and partly due to delays in partner project in warm perfusion.

Income

The gross margin for non-durable goods during the quarter was 81 (77) percent. The increase is mainly attributable to changes in product mix. The total gross margin during the quarter was 76 (74) percent.

Operating income before depreciation and amortization (EBITDA) amounted to SEK -5.5 (8.1) million, corresponding to an EBITDA margin of -18 percent (14). EBITDA during the quarter was affected by costs from organizational changes of SEK -4.5 million. Adjusted for this cost, EBITDA for the quarter amounted to SEK -1.0 (12.1) million, corresponding to an EBITDA margin of -3 percent (21).

Operating income amounted to SEK -12.7 (1.9) million, after amortization and depreciation of SEK 7.3 (6.1) million. Operating income adjusted for the above costs was SEK -8.2 (5.9) million.

As communicated in March, the company introduced a cost reduction program during the second quarter. Variable costs, such as consultancy and travel costs, were significantly reduced during the quarter. However, in relation to sales, the company's total costs have increased during the quarter since certain fixed costs, such as personnel costs, was not reduced in relation to reduced sales. The company has been able to maintain good activity in R&D projects and market initiatives, and therefore no furlough has been justified. However, government grants have been received in the USA of SEK 2.4 million, which is reported as reduced personnel costs in the Sales expense and R&D function. Sales expenses in relation to sales for the quarter were 41 percent (27). R&D costs amounted to 40 percent (27) of sales. Administrative expenses amounted to 17 percent (11) of revenue.

Net of other operating revenues and expenses during the quarter amounted to SEK -6.2 (-4.7) million, whereof costs in connection with organizational changes were SEK -4.5 million. The remaining costs come from exchange rate translation effects. See Note 4 for more information.

Financial income and expenses, net, amounted to SEK -6.0 (0.5) million because of negative exchange rate effects in liquid funds.

During the quarter, SEK 13.3 (25.5) million of the development costs were capitalized as intangible assets. SEK 11.8 (14.8) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA, Europe and Australia, SEK 1.0 (1.4) million was attributable to PrimECC® and SEK 0.5 (1.4) million was attributable to product development of the rest of the product portfolio. Amortization of capitalized development costs for the quarter amounted to SEK 3.8 (3.4) million, of which SEK 3.8 (3.4) million was attributable to amortization of capitalized development costs for regulatory approvals for products within lung transplantation.

Cash flow

Cash flow from operating activities amounted to SEK 2.4 (21.0) million, primarily as a result of the Covid-19 effects on sales. SEK 13.5 (26.4) million was invested in intangible assets and SEK 0.4 (1.4) million was invested in tangible assets. Cash flow from financing activities amounted to SEK -0.1 (27.8) million net after amortization of leasing debt of SEK -1.4 million and contributions of SEK 1.3 million relating to the warrant program for the company's employees. Exchange rate translation losses in the quarter amounted to SEK -7.0 (0.7) million. Cash and cash equivalents at the end of the quarter amounted to SEK 140.0 (198.2) million.

SIGNIFICANT EVENTS DURING THE QUARTER

New CEO appointed

Dag Andersson was appointed as the new President and CEO. XVIVO Perfusion's founder and former CEO, Magnus Nilsson, remains as Senior Advisor to primarily work with R&D. Dag Andersson started his new position on June 1, 2020. 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.

Strengthened organization within IP and clinical competence

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.

The study from Lund published in Nature Communications

During the quarter, 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.

XPS[™] sold to a leading lung transplant clinic in Europe

The University Hospital AKH in Vienna, Austria, which is one of the three largest lung transplant clinics in Europe, has purchased an XPS ™. The installation of the XPS ™ took place in the beginning of June. The clinic in Vienna has more than 30 years' experience of lung transplantation and has a well-reputed lung transplant program for being a leader in the field of Ex Vivo Lung Perfusion (EVLP). Austria has the highest rate of lung transplants per million population (13.3) according to the Global Observatory on Donation and Transplantation. The Division of Thoracic Surgery in Vienna is a high volume lung transplant center with more than 100 transplantations per year.

THE PERIOD 2020 (JANUARY – JUNE)

Net Sales

The Covid-19 pandemic has had a large impact on the sales and product mix during the period. During Mars, April and May, the decline was severe. Total net sales in the period amounted to SEK 76.9 (104.1) million, corresponding to a decrease of 26 percent in SEK and 28 percent in local currency. XVIVO Perfusion's net sales of non-durable goods* in the period amounted to SEK 72.2 (97.3) million, corresponding to a decrease of 26 percent in SEK and 28 percent in local currency. Sales of warm perfusion products were affected during the period, partly due to fewer EVLP:s being performed and partly due to delays in partner project in warm perfusion.

Total sales from warm perfusion (STEEN Solution™, XPS™, LS™, and products and services related to the use of the XPS™ and LS™) accounted for 35 (47) percent of the total sales. Warm perfusion sales from non-durable goods (STEEN Solution™, products and services related to the use of the XPS™ and LS™) accounted for 31 (44) percent of the total sales of non-Durable goods.

Income

The gross margin for non-durable goods during the period was 80 percent (77). The increase is mainly attributable to changes in product mix. The total gross margin during the period was 76 percent (75).

Operating income before depreciation and amortization (EBITDA) amounted to SEK 2.1 (11.3) million, corresponding to an EBITDA margin of 3 percent (11). EBITDA was affected by costs from organizational changes of SEK -4.5 million, while a resolution of cost provision for share-based bonus program for employees outside Sweden contributed positively with SEK 2.5 million. EBITDA adjusted for these items amounted to SEK 4.1 (20.8) million, corresponding to an EBITDA margin of 5 percent (20).

As communicated in March, the company introduced a cost reduction program during the second quarter and variable costs, such as consultancy and travel costs, were significantly reduced. However, in relation to sales, the company's total costs have increased during the period since certain fixed costs, such as personnel costs, was not reduced in relation to reduced sales. The company has been able to maintain good activity in R&D projects and market initiatives, and therefore no furlough has been justified. However, government grants have been received in the USA of SEK 2.4 million, which is reported as reduced personnel costs in the Sales expense and R&D function. Sales expenses in relation to sales for the period were 35 percent (27). R&D costs amounted to 38 percent (27) of sales. Administrative expenses amounted to 14 percent (11) of sales.

Other operating revenues and expenses, net, during the period were SEK -4.2 (-11.0) million. The item primarily consists of the costs from organizational changes, SEK -4.5 million, the resolution of cost provision for share-based bonus programs for employees outside Sweden, SEK 2.5 million, and negative currency translation effects. See Note 4 for more information.

During the period, SEK 28.5 (36.5) million of the development costs were capitalized as an intangible asset. SEK 24.8 (23.6) million attributable to investments in the Heart transplant project with aim of marketing approval in the USA, Europe and Australia, SEK 2.5 (1.6) million was attributable to PrimECC® and SEK 1.2 (1.4) million was attributable to product development of the rest of the product portfolio. Amortization of capitalized development costs for the period amounted to SEK 7.8 (6.0) million, of which SEK 7.8 (6.0) 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 period amounted to SEK 11.6 (21.1) million, primarily due to the Covid-19 effect on sales. SEK 28.9 (37.7) million was invested in intangible assets and SEK 0.8 (1.8) million was invested in tangible assets. Cash flow from financing activities amounted to SEK -1.6 (27.0) million net after amortization of leasing debt of SEK -2.9 million and contributions of SEK 1.3 million relating to the warrant program for the company's employees. Cash and cash equivalents at the end of the period amounted to SEK 140.0 (198.2) million.

Financing

XVIVO Perfusion's equity/assets ratio is strong and amounted to 92 (89) percent at the end of the period. Total credit facilities consist of an overdraft facility that at the end of the period amounted to SEK 30 (30) million, of which SEK 0.0 (0.0) million

Operating income amounted to SEK -12.7 (0.1) million, after amortization and depreciation of SEK 14.8 (11.2) million. Operating income for the period, adjusted for the items above, was SEK -10.7 (9.6) million.

^{*} See note 2 for revenue per segment.

was utilized. During the period, the company prolonged its leases for premises, which, in accordance with the accounting standard IFRS 16 Leases, has resulted in additional lease liabilities of SEK 6.0 million. Lease liabilities at the end of the period amounted to SEK 8.6 (7.3) million.

SIGNIFICANT EVENTS DURING THE QUARTER

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

As XVIVO Perfusion has reported earlier, the company has developed a new, ready-to-use version of its cold preservation product for lungs, called Perfadex® Plus. The advantage of Perfadex® Plus is that it is a ready-to-use solution that is used without the clinic adding buffer and calcium ions before use. This facilitates administration and reduces the risk of improper use. The product was launched in the principal markets, the US and Europe in 2018 and is now available in all key markets globally. Patent applications for Perfadex® Plus have been submitted in all important markets and in 2019 the European patent authority approved the patent for Perfadex® Plus in Europe.

In order to improve safety and ease of use of Perfadex[®] Plus, a new Click Port system on the bag have been developed. The new Click Port easily connects the tubing spike-free to the bag with one simple click by using the XVIVO Click Adapter.

Perfadex® Plus is the market gold standard for lung preservation and its´ predecessor Perfadex has been marketed by XVIVO Perfusion since 1999. It is used for cold preservation of lungs, which is done in order to rinse the lung from donor blood and to keep the donated lungs in good condition at a cold temperature during transportation and preservation before transplantation. Perfadex® Plus is used in the majority of all lung transplantations performed globally and is estimated to have a worldwide market share of approximately 90 percent.

XPS[™] sold to paediatric transplantation clinic in Italy

A paedriatic transplantation clinic in Rome, Italy, has purchased an XPSTM. This is the first XPSTM for a paedriatic hospital. There are approximately 200 lung transplants performed every year in Italy, whereof today only a few are pediatric lung transplants. The XPSTM and EVLP technology (Ex Vivo Lung Perfusion) will open up to be able to expand the use of donated lungs for transplantation for children with terminal lung diseases.

The company's studies for PrimECC® and cardiac preservation in Europe are ready to include the first patient

The two planned studies with PrimECC® and cardiac preservation prior to transplantation in Europe are ready to include the first patients. These two studies have not been able to start during the period, due to the fact that clinics in Europe temporarily have paused all clinical trials during the Covid-19 pandemic. The

company has prioritized to maintain competence and resources in the projects, to enable a strong investment once the studies will start, which is expected to happen during the third quarter:

OUTLOOK FOR 2020

The first half of 2020 has been affected by the ongoing Covid-19 pandemic as the number of lung transplants has decreased. In March, April and May, the downturn was severe. In the important markets, the company has seen some recovery in the US from May and in Europe from June. Both Australia and Canada have had low levels of lung transplantations throughout the second quarter. However, the company saw some recovery in the end of June. In addition, the company experienced considerable caution among transplant clinics when using warm perfusion products (XPS™, STEEN Solution™ and other sterile products for hot lung perfusion) during the period March-June. The company currently estimates that the number of transplants, and thus the demand for XVIVO Perfusion's products, will gradually recover during the third quarter. The impact on sales in the third and fourth guarters will depend on the magnitude of the Covid-19 pandemic affecting intensive care in the various markets, especially in Europe and North America. Transplantation is a life-sustaining treatment and transplants are prioritized by health authorities around the world. Therefore, the company believes that the long-term effect on demand for transplant products will be unchanged. In order to adapt the cost situation to a temporarily reduced demand, XVIVO Perfusion carries out a cost reduction program.

The Covid-19 pandemic has also meant that clinics in the world have temporarily paused clinical research. The company will continue its development in lung transplantation, heart transplantation and PrimECC® with the goal of starting clinical multicenter studies in Europe, USA and Australia as soon as clinics allow clinical research again. Both the heart transplant study in Europe and the PrimECC® study in Sweden are ready to start and the company estimates that this can be done in the third quarter. Expenditure related to the development of heart transplantation and PrimECC® will be capitalized on an ongoing basis.

THE COMPANY IN BRIEF

Background

Organ transplantation is the last resort for patients with endstage 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. Currently, the company's product, Perfadex[®] Plus, has a market share of approximately 90 percent in the traditional preservation of lungs for transplantation. 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.

Lung transplantation

A great problem in transplantation healthcare is the lack of available lungs. Currently in 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 the body. In clinical use in the US, Europe, Australia, and Canada, it has emerged 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.

Heart transplantation

Based on the world leading research of Professor Stig Steen and Igelösa, XVIVO Perfusion's heart transplantation competence center in Lund (Sweden) develops 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. Future focus is to perform clinical multicenter studies and use the documentation of these studies as a basis for applications for regulatory approvals for the products on all major markets.

Other indications

The company also invests in preclinical and clinical research in transplantation of liver and kidney and in perfusion of organs remaining in the body, for example, drug administration to isolated organs and priming solutions for heart-lung machines.

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 the 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 quarter, the number of employees was 60, of whom 25 were women and 35 were men. Of these, 35 people were employed in Sweden and 25 outside Sweden. In addition, the company uses around 5 consultants.

Information on transactions with related parties

During the period, transactions with the Board member Folke Nilsson was conducted amounting to SEK 36 thousand for consultancy services in 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 quality, 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. Including financial risks are the currency risk for the business.

The most important strategic and operative risks affecting the company are described in the 2020 annual report, which can be found 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 of the lungs there are slightly less activity during the summer months.

Events after the end of the reporting period

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

Gothenburg July 10, 2020

Dag Andersson Gösta Johannesson
CEO and Board member Chairman of the board

Camilla Öberg Folke Nilsson
Board member Board member

Yvonne Mårtensson 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.

Calendar:

Interim Report January-September 2020: Friday, October 23, 2020

Report on Operations 2020:Thursday, January 28, 2021 Interim Report January-March 2021:Wednesday, April 21, 2021

Interim Report January-June 2021: Friday, July 9, 2021 Interim Report January-September 2021: Thursday, October 28, 2021

Report on Operations 2021: Thursday, January 27, 2022

For further information, please contact

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This information is information that XVIVO Perfusion AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Market Securities Act. The information was submitted for publication, through the agency of the contact person set out above on July 10, 2020 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

65/75/10/10/10/10/10		nuary - June		pril - June	Whole year
SEKTHOUSANDS	2020	2019	2020	2019	2019
Net sales	76 848	104 087	30 393	56 437	220 837
Cost of goods sold	-18 364	-25 523	-7 29 I	-14 789	-58 024
Gross income	58 484	78 564	23 102	41 648	162 813
Selling expenses	-27 200	-28 038	-12 360	-15 957	-60 786
Administrative expenses	-10717	-11 558	-5 069	-6 148	-24 739
Research and development costs	-29 059	-27 860	-12 186	-12 898	-62 65 I
Other operating revenues and expenses*	-4 194	-11041	-6 196	-4716	-10 697
Operating income	-12 686	67	-12 709	I 929	3 940
Financial income and expenses	503	I 978	-6 047	527	I 350
Income after financial items	-12 183	2 045	-18 756	2 456	5 290
Taxes	2 708	-133	2 738	-229	-351
Net income	-9 475	1 912	-16 018	2 227	4 939
Attributable to					
Parent Company's shareholders	-9 475	1912	-16 018	2 227	4 939
Earnings per share, SEK	-0,36	0,07	-0,60	0,08	0,19
Earnings per share, SEK**	-0,36	0,07	-0,60	0,08	0,18
Average number of outstanding shares	26 600 496	26 484 446	26 600 496	26 532 296	26 518 546
Average number of outstanding shares**	26 600 496	26 799 996	26 600 496	26 879 496	26 799 996
Number of shares at closing day	26 600 496	26 600 496	26 600 496	26 600 496	26 600 496
Number of shares at closing day**	26 600 496	26 879 496	26 600 496	26 879 496	26 879 496
EBITDA	2 098	11 296	-5 452	8 055	28 800
Amortization	-8 222	-6 333	-4 107	-3 618	-14 539
Depreciation	-6 562	-4 896	-3 150	-2 508	-10 321
Operating income	-12 686	67	-12 709	I 929	3 940

 $[\]ensuremath{^{*}}$ See note 4 for "Other operating revenues and expenses"

CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME

		inuary - June		April - June		
SEKTHOUSANDS	2020	2019	2020	2019	2019	
Net income	-9 475	1 912	-16 018	2 227	4 939	
Other comprehensive income						
Items that may be reclassified to the income statement						
Exchange rate differences	423	2 881	-5 226	30	3 72 I	
Tax attributable to items that have been transferred, or can be						
transferred to net income	-146	-370	319	-20	-514	
Total other comprehensive income, net after tax	277	2 5 1 1	-4 907	10	3 207	
Total comprehensive income	-9 198	4 423	-20 925	2 237	8 146	
Attributable to						
Parent Company's shareholders	-9 198	4 423	-20 925	2 237	8 146	

 $[\]ensuremath{^{**}}$ After dilution. See note 5 for information on warrant programs.

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEKTHOUSANDS	June 30, 202	June 30, 2019	Dec 31,2019
ASSETS			
Goodwill	65 78	65 752	65 773
Capitalized development expenditure	287 28	241 021	266 517
Other intangible fixed assets	611.	4410	6219
Fixed assets	23 98	21 578	23 554
Financial assets	15 19	1 14 270	12 539
Total non-current assets	398 36	347 03 1	374 602
Inventories	48 02·	46 634	43 87 I
Current receivables	34 02'	52 570	56 068
Liquid funds	139 99	198 215	159 946
Total current assets	222 04	297 419	259 885
Total assets	620 40	644 450	634 487
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity, attributable to the Parent Company's shareholders	569 65	573 541	577 521
Long-term interest-bearing leases	2 58.	3 929	2 154
Long-term non-interest-bearing liabilities	2 88	3 555	2213
Short-term interest-bearing leases	6 06	3 334	3 396
Short-term non-interest-bearing liabilities	39 22	60 09 1	49 203
Total shareholders' equity and liabilities	620 40	644 450	634 487

CONSOLIDATED KEY RATIOS

	Ja	nuary - June		April - June		
	2020	2019	2020	2019	2019	
Gross margin non-Durable goods, %	80	77	81	77	77	
Gross margin, %	76	75	76	74	74	
EBITDA,%	3	11	-18	14	13	
Operating margin,%	-17	0	-42	3	2	
Net margin, %	-12	2	-53	4	2	
Equity/assets ratio, %	92	89	92	89	91	
Income per share, SEK	-0,36	0,07	-0,60	0,08	0,19	
Shareholders' equity per share, SEK	21,42	21,66	21,42	21,62	21,71	
Share price on closing day, SEK	180,00	198,60	180,00	198,60	170,00	

See page 16-17 for key ratios definition and reconciliation of alternative key figures.

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

	Ja	nuary - June	Ap	April - June		
SEKTHOUSANDS	2020	2019	2020	2019	2019	
Income after financial items	-12 184	2 045	-18 758	2 456	5 290	
Adjustment for items not affecting cash flow	18 660	9 785	17 287	5 90 1	28 862	
Paid taxes	-379	-1 561	428	-769	-2 945	
Change in inventories	-4 279	-8 855	894	I 405	-8 478	
Change in trade receivables	23 456	2419	9 82 I	-1 252	-542	
Change in trade payables	-13 659	17313	-7 286	13 278	7318	
Cash flow from operating activities	11615	21 146	2 386	21 019	29 505	
Cash flow from investing activities	-29 746	-39 479	-13 894	-27 819	-83 844	
Cash flow from financing activities	-1 629	26 995	-140	27 796	25 55 1	
Cash flow for the period	-19 760	8 662	-11 648	20 996	-28 788	
	150.047	107.074	150,700	177 402	107.074	
Liquid funds at beginning of period	159 946	187 064	158 608	176 483	187 064	
Exchange rate difference in liquid funds	-193	2 489	-6 967	736	I 670	
Liquid funds at end of period	139 993	198 215	139 993	198 215	159 946	

CONSOLIDATED CHANGES IN SHAREHOLDERS EQUITY

		Attributable to Parent Company's shareholders						
sekthousands	Share capital	Other paid in capital	Reserves	Retained ear- nings incl. profit for the year	Sum shareholders' equity			
Shareholders' equity as of I January, 2019	675	486 860	13 021	39 921	540 477			
Total comprehensive income Jan - June, 2019			2511	1912	4 423			
Share warrent program Issuing of new shares efter deduction of incremental costs		I 236			I 236			
directly related to issuing new shares net of tax	5	27 400			27 405			
Shareholders' equity as of 30 June, 2019	680	515 496	15 532	41 833	573 541			
Total comprehensive income July - December, 2019			696	3 027	3 723			
Share warrent program Issuing of new shares after deduction of incremental costs		361			361			
directly related to issuing new shares net of tax		-104			-104			
Shareholders' equity as of 31 december, 2019	680	515 753	16 228	44 860	577 521			
Total comprehensive income January - June, 2020			277	-9 476	-9 199			
Share warrent program Issuing of new shares efter deduction of incremental costs directly related to issuing new shares net of tax		33			I 331			
Shareholders' equity as of 30 june, 2020	680	517 084	16 505	35 384	569 653			

CONDENSED CONSOLIDATED STATEMENT OF NET INCOME PER QUARTER

SEKTHOUSANDS	Apr - Jun 2020	Jan - Mar 2020	Oct - Dec 2019	Jul - Sep 2019	Apr - Jun 2019	Jan - Mar 2019	Oct - Dec 2018	Jul - Sep 2018
Net sales	30 393	46 455	62 416	54 334	56 437	47 650	58 389	40 914
Cost of goods sold	-7 291	-11 073	-16710	-15 791	-14 789	-10 734	-16615	-9 876
Gross income	23 102	35 382	45 706	38 543	41 648	36 916	41 774	31 038
Selling expenses	-12 360	-14 840	-18 372	-14 376	-15 957	-12 081	-14 166	-11 846
Administrative expenses	-5 069	-5 648	-7 152	-6 029	-6 148	-5 410	-7 808	-5 513
Research and development costs	-12 186	-16 873	-17 964	-16 827	-12 898	-14 962	-12 560	-11 734
Other operating revenues and expenses*	-6 196	2 002	-622	966	-4716	-6 325	-1 126	-1 207
Operating income	-12 709	23	I 596	2 277	I 929	-1 862	6 1 1 4	738
Financial income and expenses	-6 047	6 550	-3 838	3 2 1 0	527	I 451	I 208	-803
Income after financial items	-18 756	6 573	-2 242	5 487	2 456	-411	7 322	-65
Taxes	2 738	-30	340	-558	-229	96	-2 437	164
Net income	-16 018	6 543	-1 902	4 929	2 227	-315	4 885	99
Attributable to								
Parent Company's shareholders	-16018	6 543	-1 902	4 929	2 227	-315	4 885	99
Earnings per share, SEK	-0,60	0,25	-0,07	0,19	0,08	-0,01	0,19	0,00
Earnings per share, SEK**	-0,60	0,25	-0,07	0,18	0,08	-0,01	0,19	0,00
Average number of outstanding shares	26 600 496	26 600 496	26 600 496	26 600 496	26 532 296	26 402 496	26 402 496	26 402 496
Average number of outstanding shares**	26 600 496	26 600 496	26 879 496	26 879 496	26 879 496	26 720 496	26 402 496	26 786 496
Number of shares at closing day	26 600 496	26 600 496	26 600 496	26 600 496	26 600 496	26 402 496	26 402 496	26 402 496
Number of shares at closing day**	26 600 496	26 600 496	26 879 496	26 879 496	26 879 496	26 879 496	26 402 496	26 879 496
EBITDA	-5 452	7 550	8 479	9 025	8 055	3 241	10 485	5 207
Amortization	-4 107	-4 115	-4 107	-4 099	-3618	-2715	-2 725	-2 736
Depreciation	-3 150	-3 412	-2 776	-2 649	-2 508	-2 388	-1 646	-1 733
Operating income	-12 709	23	I 596	2 277	I 929	-1 862	6 1 1 4	738

^{*} See note 4 for "Other operating revenues and expenses"

CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME PER QUARTER

sekthousands	Apr - Jun 2020	Jan - Mar 2020	Oct - Dec 2019	Jul - Sep 2019	Apr - Jun 2019	Jan - Mar 2019	Oct - Dec 2018	Jul - Sep 2018
Net income	-16 018	6 543	-1 902	4 929	2 227	-315	4 885	99
Other comprehensive income Items that may be reclassified to the income statement								
Exchange rate differences Tax attributable to items that have been transferred, or can be transferred to	-5 226	5 649	-3 691	4 53 I	30	2 85 I	l 126	-801
net income	319	-465	343	-487	-20	-350	-164	81
Total other comprehensive income,								
net after tax	-4 907	5 184	-3 348	4 044	10	2 501	962	-720
Total comprehensive income	-20 925	11 727	-5 250	8 973	2 237	2 186	5 847	-621
Attributable to								
Parent Company's shareholders	-20 925	11727	-5 250	8 973	2 237	2 186	5 847	-621

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

CONDENSED INCOME STATEMENT FOR THE PARENT COMPANY

	Ja	nuary - June	Арі	April - June		
SEKTHOUSANDS	2020	2019	2020	2019	2019	
Net sales	58 547	82 254	25 373	42 675	169 608	
Cost of goods sold	-13 757	-19 402	-4 65 I	-7 904	-50 677	
Gross income	44 790	62 852	20 722	34 77 I	118 931	
Selling expenses	-16 421	-18 473	-7 788	-10 290	-36 502	
Administrative expenses	-9 681	-7 936	-4 664	-4518	-18 485	
Research and development costs	-31 353	-32 369	-17 145	-16 420	-65 937	
Other operating revenues and expenses	-5 858	-818	-5 896	-349	-181	
Operating income	-18 523	3 256	-14 771	3 194	-2 174	
Financial income and expenses	I 594	4 20 I	-7 333	904	4 774	
Income after financial items	-16 929	7 457	-22 104	4 098	2 600	
Year end dispositions	-	-	-	-	-2 300	
Taxes	3 409	-586	3 409	-282	-299	
Net income	-13 520	6 87 1	-18 695	3 816	1	

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 9 915 (7 890) thousand, of which SEK 4 900 thousand (4 413) for the quarter.

CONDENSED BALANCE SHEET FOR THE PARENT COMPANY

SEKTHOUSANDS	June 30, 2020	June 30, 2019	Dec 31,2019
ASSETS			
Intangible fixed assets	224 707	180 605	206 205
Fixed assets	6 756	6 303	7 924
Financial assets	186 921	199 142	194 166
Total non-current assets	418 384	386 050	408 295
Inventories	21 602	16 441	15 070
Current receivables	21 833	23 887	34 352
Cash and bank	116814	186 539	150 362
Total current assets	160 249	226 867	199 784
Total assets	578 633	612 917	608 079
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	535 961	554 748	548 150
Untaxed reserves	4 200	10 150	4 200
Provisions	1 315	I 322	6 734
Short-term non-interest-bearing liabilities	37 157	46 697	48 995
Total shareholders' equity and liabilities	578 633	612 917	608 079

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 I. 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 data per segment, Group

	January - June								
	Net sales Durable		Durable	goods	Total cons	olidated			
SEK Thousands	2020	2019	2020	2019	2020	2019			
Net sales	72 89	97 319	4 659	6 768	76 848	104 087			
Cost of goods sold	-14415	-21 991	-3 949	-3 532	-18 364	-25 523			
Gross income	57 774	75 328	710	3 236	58 484	78 564			

Gross income	22 687	39 068	415	2 580	23 102	41 648
Cost of goods sold	-5 316	-11 462	-1 975	-3 327	-7 291	-14 789
Net sales	28 003	50 530	2 390	5 907	30 393	56 437
SEK Thousands	2020	2019	2020	2019	2020	2019
	Net sales of non- Durable goods		Durable goods		Total consolidated	
	April - June					

Note 3. Financial instruments

The Group's financial assets and liabilities valuated at acquisition value amount to SEK 174 (251) million and SEK 39 (63) million respectively. Fair value of the Group's financial assets and liabilities is assessed to correspond to the book value.

Note 5. Share warrant programs

In total there are 725.000 outstanding warrants in two programs.

The Annual General Meeting of 2019 resolved to issue no more than 315.000 warrants (series 2019/2021), with the right to subscribe for a maximum of 315.000 new shares to employees of the XVIVO Perfusion Group. Of these warrants, all 351,000 were subscribed by employees. Each warrant entitles the holder 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 no more than 408.000 warrants (series 2020/2022), with the right to subscribe for a maximum of 408.000 new shares to employees of the XVIVO Perfusion Group. At the time of submission of this report, 374,000 warrants were subscribed by employees. Each warrant entitles the holder to subscribe for a new share in May 2022, at a price of SEK 205.88.

During the period January-June 2020, neither the average share price for the period, nor the closing price at period end, exceeded the exercise price of warrant program series 2019/2021 or series 2020/2022, whereby none of the warrant programs result in a dilution for existing shares.

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 option programs. The cash-based programs should, as far as practically possible, be designed to correspond to the Swedish option 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 option program. The cost is recognized under "Other operating revenue and expenses" and is described in note 4.

Note 4. Other operating revenues and expenses

TSEK	Apr - Jun 2020	Jan-Mar 2020	Oct - Dec 2019	Jul - Sep 2019	Apr - Jun 2019	Jan-Mar 2019	Oct - Dec 2018	Jul - Sep 2018
Cost of cash-based incentive program for								
employees outside Sweden	-	2 541	237	2 253	-4 000	-5 536	812	-812
Cost of reorganization	-4 498	-	-	-	-	-	-	-
Other	-1 698	-539	-859	-1 287	-716	-789	-1 938	-395
Total	-6 196	2 002	-622	966	-4716	-6 325	-1 126	-1 207

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

	Janu	ary - June	Apr	l - June	Whole year
sekthousands	2020	2019	2020	2019	2019
Operating income	-12 686	67	-12 709	I 929	3 940
Amortization	8 222	6 333	4 107	3618	14 539
Depreciation	6 562	4 896	3 150	2 508	10 321
EBITDA	2 098	11 296	-5 452	8 055	28 800

Gross margin

Gross margin %	76	75	76	74	74
Gross income	58 484	78 564	23 102	41 648	162 813
Cost of goods sold	-18 364	-25 523	-7 291	-14 789	-58 024
Operating expenses					
Net sales	76 848	104 087	30 393	56 437	220 837
Operating income					
SEKTHOUSANDS	2020	2019	2020	2019	2019
	Janu	ary - June	Apr	il - June	vvhole year

Gross margin non-Durable goods

Gross margin non-Durable goods						
sekthousands	January - June 2020 2019		Apr 2020	Whole year 2019		
Operating income Net sales of non-Durable goods	72 189	97 319	28 003	50 530	206 857	
Operating expenses Cost of non-Durable goods sold	-14 415	-21 991	-5 316	-11 462	-47 439	
Gross income, non-Durable goods Gross margin,	57 774	75 328	22 687	39 068	159 418	
non-Durable goods %	80	77	81	77	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

SEKTHOUSANDS Shareholders' equity	June 30, 2020 569 653	2019 573.541	December 31, 2019
Total assets	620 408	644 450	634 487
Equity/assets ratio %	92	89	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:

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

Clinical study/trial

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

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.

Perfusion

Passage of a fluid through an organ's blood vessels.

Evaluation

Evaluation of the function of an organ.

Preservation

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

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.

In vivo

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

EVLP or Ex Vivo Lung Perfusion

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

Hypo-thermic non-ischemic perfusion of a heart

Circulation of a cold, donated heart with addition of oxygen and necessary nutrition's during transport to the recipient.

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.

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 Ill 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.

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.

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.

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).

CURRENT R&D PORTFOLIO

PROJECT

DESCRIPTION

STATUS

DEVELOPMENT PROJECTS

Heart transplantation



What primarily limits how many 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 Perfusion is working in collaboration with Professor Stig Steen to develop a holistic solution consisting of fluids and a machine that preserve the donated heart's function better while it is outside the body, which could make more hearts usable for transplantation. This next-generation solution may contribute to more patients in the final stages of heart failure receiving a transplant, thus gaining a longer life and higher quality of life.

The company is working on initiating a programme of clinical multicentre studies. These studies will form the basis of application for regulatory approval of the products in all the large markets in the world. In a European study it is planned that 202 patients in eight centres in seven countries will be assigned at random to receive a transplant either in the form of a donated heart transported using XVIVO's method or preserved using the traditional icebox method. XVIVO anticipates that it will be able to start the study during the third quarter, though this will be dependent on the development of the COVID-19 pandemic. 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" from the FDA. This study is also planned to start during the second half of 2020. Supplementary studies on the products initiated by investigators are being started in Australia and Sweden as

PrimECC



PrimECC is a fluid that has been developed in collaboration with Professor Stig Steen in Lund and is intended to be used in a so-called heart-lung machine. This machine completely takes over the function of the heart and the lungs during the several hundred thousand heart operations performed each year. Before the heart-lung machine is connected to the patient, the machine must be filled with fluid so that there is no air in the system. When the procedure is started, this fluid will be given to the patient as some of the patient's blood fills the machine. Simple saline solutions are as a rule used for this purpose today. It is hoped that PrimECC with its optimized properties will reduce side effects related to the use of heart-lung machines by protecting the body's organs.

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. During 2016 and 2017 a randomized clinical study was performed on 80 patients at Sahlgrenska University Hospital in Gothenburg and this indicated positive effects from the use of PrimECC. During 2020 a larger scale study is planned with a view to mapping these effects more thoroughly. The study will include 366 patients who will undergo a heart operation at one of the Swedish university hospitals and it is estimated that it will be initiated in the third quarter of 2020, initially at Sahlgrenska University Hospital. The company will wait with the launch of the product until the study results have been analysed.

RESEARCH PROJECTS

Liver transplantation



As for other organs, there is a lack of transplantable livers. Together with researchers, XVIVO Perfusion is investigating methods to use STEEN Solution in this area. By preserving the donated liver's function in an optimal manner and evaluating livers, potentially more well-functioning organs could be transplanted.

In an exploratory clinical phase. The first clinical trials on warm perfusion of the liver using STEEN Solution before transplantation have been successfully carried out on approximately thirty occasions in Toronto, Canada. During 2020 the company will evaluate starting clinical studies on STEEN Solution for liver transplantation.

Kidney transplantation



As for other organs, there is a lack of transplantable kidneys. Together with researchers, XVIVO Perfusion is investigating methods to use STEEN Solution in this area. By preserving the donated kidney's function in an optimal manner and evaluating kidneys, potentially more well-functioning organs could be transplanted.

In an exploratory clinical phase. The first trials on kidney transplantation including the use of STEEN Solution have been carried out in Toronto, Canada, in 15 patients who had received a transplant. During 2020 the company will evaluate starting clinical studies on STEEN Solution for kidney transplantation.

Xenotransplantation



Xenotransplantation means that organs from another species than human beings are used for transplantation. The method is currently at the research stage for several organs.

XVIVO Perfusion's method for preserving the heart's function is currently used by two world-leading research groups, where gene-modified organs from pigs are transplanted to primates. In one case that has received the attention of the research world, the primate lived for more than 180 days (see article in Nature on December 5, 2018).

XVIVO PERFUSION'S PRODUCTS

WARM PERFUSION WARM PERFUSION COLD PERFUSION STEEN Solution™ PERFADEX® Plus XVIVO LS™, Durable goods XVIVO Organ Chamber™ XVIVO Silicone Tubing Set™ XVIVO Disposable Lung Kit™ XVIVO Disposable Lung Set™



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