



REPORT ON OPERATIONS 2019

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 approximately 90 percent in the traditional cold 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. XVIVO Perfusion employs around 50 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.



A HISTORIC YEAR ENDED WITH A QUARTER OF SALES RECORDS

FOURTH QUARTER 2019 (OCT - DEC)

- Net sales of non-durable goods* in the quarter amounted to SEK 59.4 (52.3) million, corresponding to an increase of 14 percent in SEK and 6 percent in local currency. Total net sales (incl. durable goods) in the quarter amounted to SEK 62.4 (58.4) million, corresponding to an increase of 7 percent in SEK and 0 percent in local currency.
- Sales from warm perfusion** represented 48 percent (50) 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 amounted to SEK 8.3 million (9.7), corresponding to an EBITDA margin of 13 percent (17). Reported EBITDA amounted to SEK 8.5 (10.5) million, corresponding to an EBITDA margin of 14 percent (18).
- Reported operating income amounted to SEK 1.6 (6.1) million, after amortization and depreciation of SEK 6.9 (4.4) million. Operating income adjusted for the share-based bonus program was SEK 1.4 million (5.3).
- Net income amounted to SEK -1.9 (4.9) million, resulting in earnings per share of SEK -0.07 SEK (0.19).
- Cash flow from operating activities during the quarter amounted to SEK -7.2 (-2.4) million. Cash flow from investing activities amounted to SEK -26.3 (-11.9) million.
- Breakthrough Device Designation granted from the FDA for the XVIVO Heart Preservation System.
- An Australian subsidiary was established and a third XPS™ was delivered to the country.
- XVIVO's issue of warrants for employees of series 2019/2021 was fully subscribed.

THE PERIOD 2019 (JAN - DEC)

- Net sales of non-durable goods* in the period amounted to SEK 206.9 (172.7) million, corresponding to an increase of 20 percent in SEK and 12 percent in local currency. Total net sales (incl. durable goods) in the period amounted to SEK 220.8 (187.9) million, corresponding to an increase of 12 percent in SEK and 10 percent in local currency.
- Sales from warm perfusion** represented 45 percent (43) 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 amounted to SEK 35.8 million (33.7), corresponding to an EBITDA margin of 16 percent (18). Reported EBITDA amounted to SEK 28.8 (30.9) million, corresponding to an EBITDA margin of 13 percent (16).
- Reported operating income amounted to SEK 3.9 (14.0) million, after amortization and depreciation of SEK 24.9 (16.9) million. Operating income adjusted for the share-based bonus program was SEK 10.9 million (16.8).
- Net income amounted to SEK 4.9 (12.7) million, resulting in earnings per share of SEK 0.19 (0.48).
- Cash flow from operating activities for the period amounted to SEK 29.5 (23.6) million. Cash flow from investing activities amounted to SEK -83.8 (-53.2) million.
- XVIVO has received Premarket approval (PMA) from the FDA for STEEN Solution™ and XPS™. The PMA approval was the first of its kind in the world.
- Perfadex® Plus received patent approval in Europe.
- At ISHLT (International Society for Heart and Lung Transplantation), the positive results from the first six heart transplant patients from the study at Lund University Hospital were presented.
- XVIVO and MyCartis engage to develop a fast diagnostic test to assess the quality of donated organs before transplantation.
- XVIVO's patents for the heart preservation fluid was approved in the US and Europe.
- The Swedish MPA has given approval to begin clinical studies with the company's new products for heart preservation. Applications have been submitted to all other participating EU countries.
- SEK 27 million shares was issued because of warrants being exercised.
- Reimbursement for the whole EVLP process granted in France.
- Five XPS™ were delivered during the period. At the end of the period 51 hospitals had access to either XPS™ or LS™. During the period, Canada became a new country with XPS™.

MILESTONES PASSED DURING THE YEAR

XVIVO has received Premarket approval (PMA) from the FDA for STEEN Solution™ and XPS™

XVIVO's patents for the heart preservation fluid was approved in the US and Europe

Perfadex® Plus received patent approval in Europe

The Swedish MPA has given approval to begin clinical studies with the company's new products for heart preservation

At ISHLT (International Society for Heart and Lung Transplantation), the positive results from the first six heart transplant patients from the study at Lund University Hospital were presented

Breakthrough Device Designation granted from the FDA for the XVIVO Heart Preservation System

Net sales of non-durable goods passed 200 MSEK

XVIVO established an Australian wholly owned subsidiary

CONFERENCE CALL

CEO Magnus Nilsson will present the report in a conference call at 2 p.m. CET on Thursday, January 30, 2020.
Telephone UK: +44 (0) 3333 0008 04 or USA: +1 631 913 1422, enter code 31640247#.



The PMA approved
XPS-machine

CEO'S COMMENTS



We are delighted to be able to summarize the most successful year ever for XVIVO Perfusion, with strong sales development, the company's first PMA approval (XPS™ with STEEN Solution™) and great progress in our other important product areas as well – heart transplantation and PrimECC®. Total sales

for 2019 amounted to SEK 221 million, driven by sales of non-durable goods which showed a growth of +20 percent. Most of the strong sales growth have come from the warm perfusion of lungs area, but cold preservation also displays good growth. A milestone was passed when sales of our input products were in excess of SEK 200 million for the first time. We were particularly pleased to observe that growth in Europe clearly accelerated during the year. This means that for the 29th quarter in a row (all quarters as a listed company) XVIVO displayed positive sales growth, a good gross margin and positive EBITDA. This is in parallel with making significant investments in R&D, in regulatory competence and in expansion of our customer support organization.

In addition to the PMA approval of XPS™ with STEEN Solution™ in the US, other important milestones were passed within the field of lung transplantation: the start-up of a subsidiary in Australia when a third XPS™ was sold in the country, and Perfadex® Plus, which is an improved "ready-to-use" version of Perfadex®, the company's largest product, obtained patent approval in Europe. XVIVO continues to develop the technology for the warm perfusion of lungs, both under its own management and through collaboration with partners, so as to be the leader in this product area in the future as well.

Very important steps have been taken in the development of the future growth areas – heart transplantation and PrimECC®. In the field of heart transplantation, good results were presented at the large transplantation conference during the year, ISHLT, from the initial part of a heart preservation study at Lund University Hospital using Professor Steen's first prototype. A new ready to use solution product and an improved second machine version have been constructed, tested and completed for the multicenter studies that will be started in all important markets. For the European studies, applications for approval of clinical trials were submitted earlier during the year in seven countries. These have been approved by some countries but are still being reviewed at present by some countries' medical authorities. We expect to be able to include patients in the first quarter at a number of centers. A "Breakthrough Device Designation" was received from the FDA. This will shorten the administration time for

the whole study process and for the application for market approval in the US. It was also important for the product development project that XVIVO's patent application for the heart preservation fluid has been approved in the US and Europe.

The regulatory file for the new version of PrimECC® production with new environmentally and user-friendly packaging was submitted during the third quarter. The approval of which is necessary to secure the continuation of the clinical program. The regulatory review of this change has taken a long time, due to the fact that the so-called Notified Bodies have an incredibly tough workload resulting in longer review times. This in turn is due to the fact that all Notified Bodies must be certified for the change in EU regulations for medical devices (MDR), which is planned to take place in May 2020. This type of delay is something that has affected all actors in the medical device field. As soon as the review of the regulatory file for the new version of PrimECC® production is complete, the continuation of clinical development can be initiated. The planned multicenter study, intended to widen the documentation of the product, is expected to be ongoing until the beginning of 2021 and to include 366 patients at seven clinics in Sweden.

As can be seen, in 2019 XVIVO managed to be both successful in the market and to achieve ambitious milestones in R&D, at the same time as the company has grown considerably in terms of competence and scope. This would not have been possible without our uniquely committed employees who collaborate over three continents. Despite the rapid expansion, XVIVO perfusion is still a small, firmly focused growth company with a high level of internal competence that invests the equivalent of 60 percent of sales (including what is capitalized in the balance sheet) in product development, with a view to long-term growth in the new product areas as well.

The focus for the lung transplantation area is to continue to support the transplantation clinics in their efforts to be able to treat more of the patients on the transplantation waiting lists by continuing to refine and simplify the EVLP technology and to increase the installation base of the company's EVLP machines, above all in Europe and in the new markets in Asia. In the field of heart transplantation we are fully focused on supporting the clinics in the three clinical multicenter studies (Europe, the US and Australia). In general terms, XVIVO's research focuses on continuing to lead the development of innovative solutions in the field of organ transplantation and focus on assuring that we maintain our vision that no one should die waiting for an organ.

Magnus Nilsson
CEO

FOURTH QUARTER 2019 (OCTOBER - DECEMBER)

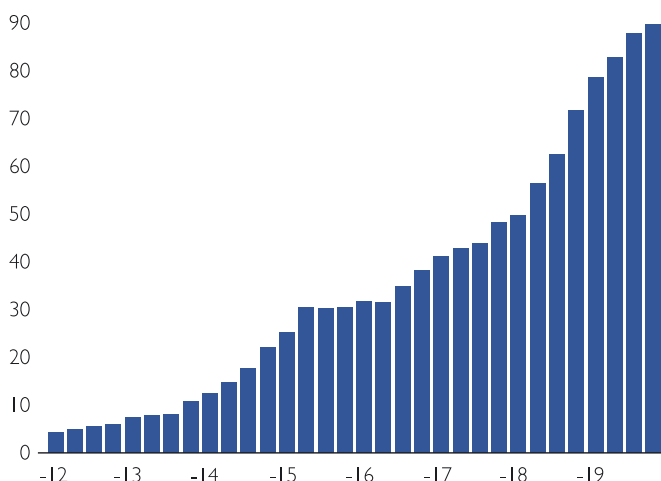
Net Sales

Total net sales in the quarter amounted to SEK 62.4 (58.4) million, corresponding to an increase of 7 percent in SEK and 0 percent in local currency. Net sales of non-durable goods* in

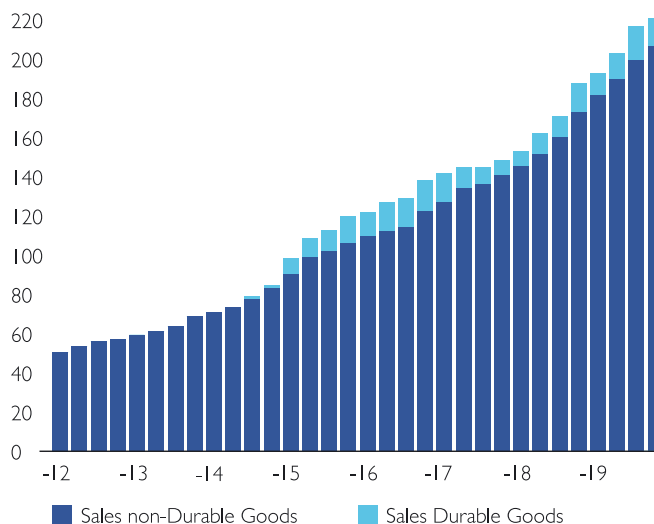
the quarter amounted to SEK 59.4 (52.3) million, corresponding to an increase of 14 percent in SEK and 6 percent in local currency.

Total sales from warm perfusion (STEEN Solution™, XPS™, LS™, and products and services related to the use of the XPS™ and LS™) accounted for 51 (55) percent of the total sales. Warm perfusion sales from non-durable goods (STEEN

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



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



COMPILATION OF NET SALES AND EBITDA

SEK THOUSANDS	January - December		October - December	
	2019	2018	2019	2018
Net Sales non-Durable Goods	206 857	172 693	59 401	52 333
Net Sales Durable Goods	13 980	15 175	3 015	6 056
Net Sales Total	220 837	187 868	62 416	58 389
Cost of Goods non-Durable Goods	-47 439	-39 406	-13 771	-11 521
Cost of Goods Durable goods	-10 585	-12 509	-2 939	-5 094
Cost of Goods Total	-58 024	-51 915	-16 710	-16 615
Gross income non-Durable Goods	159 418	133 287	45 630	40 812
Gross margin non-Durable Goods, %	77%	77%	77%	78%
Gross income Durable Goods	3 395	2 666	76	962
Gross income Total	162 813	135 953	45 706	41 774
Gross margin Total, %	74%	72%	73%	72%
Selling expenses	-60 786	-47 948	-18 372	-14 166
Administrative expenses	-24 739	-22 519	-7 152	-7 808
Research and development costs	-62 651	-47 931	-17 964	-12 560
Other operating revenues and expenses**	-10 697	-3 555	-622	-1 126
Operating Income	3 940	14 000	1 596	6 114
Depreciation of cost of goods sold	-815	-527	-208	-177
Depreciation of administrative expenses	-2 216	-1 384	-631	-348
Amortization of research and development expenses	-16 624	-10 900	-4 693	-2 737
Depreciation of other operative expenses	-5 205	-4 112	-1 351	-1 109
EBITDA	28 800	30 923	8 479	10 485
EBITDA, %	13%	16%	14%	18%

*See note 3 for segments. ** Item "Other operation revenues and expenses" for 2019 includes costs for a share based bonus program for employees based outside of Sweden. Accumulated for the period January-December 2019, the cost amounted to SEK -7 046 thousand (-2 800). During the fourth quarter the cost was positive of SEK 237 thousand (812) due to resolution of a provision. During 2018 this cost was recognized in the respective functions. See note 2 for more information.

Solution™, products and services related to the use of the XPS™ and LS™) accounted for 48 (50) percent of the total sales of non-durable goods.

Income

The gross margin for non-durable goods during the quarter was 77 (78) percent. The total gross margin during the quarter was 73 (72) percent.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 8.5 (10.5) million, corresponding to an EBITDA margin of 14 percent (18). The decrease in EBITDA compared with last year is mainly due to increased sales and R&D costs, caused by increased investments in to marketing and product development. During the fourth quarter, costs for the share-based bonus program for employees outside Sweden was positive, SEK 0.2 (0.8) million, due to a resolution of an earlier made provision. For more information see note 2. EBITDA adjusted for costs for the share-based bonus program for employees outside Sweden amounted to SEK 8.3 million (9.7), corresponding to an EBITDA margin of 13 percent (17).

Operating income amounted to SEK 1.6 (6.1) million, after amortization and depreciation of SEK 6.9 (4.4) million. Adjusted operating income for the quarter was SEK 1.4 million (5.3).

Selling expenses in relation to sales increased during the quarter to 29 (24) percent. The increase is mainly due to a larger organization, investments into marketing and the buildup of an Australian subsidiary. R&D expenses amounted to 29 (22) percent of sales. The increase of R&D expenses in relation to sales is primarily attributable to increased depreciations and the upgrade of the XPS-technology with the aim of supporting the growth within EVLP. Administrative expenses decreased to 11 (13) percent of sales.

Net of other operating revenues and expenses during the quarter were SEK -0.6 (-1.1) million. The financial net was -3,8 MSEK (1,2). The decrease compared to the comparison quarter is due to currency conversions in liquid funds.

During the quarter, SEK 17.6 (12.1) million of the development costs were capitalized as an intangible asset. SEK 14.4 (8.6) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, SEK 2.1 million (0.0) was attributable to PrimeECC and SEK 1.1 (3.5) million was attributable to product development of the rest of the product portfolio. Amortization of capitalized development costs for the quarter amounted to SEK 3.9 (2.5) million, of which SEK 2.5 (2.5) million was amortization of the HDE approval and SEK 1.4 (-) million was amortization of the PMA approval.

Cash flow

Cash flow from operating activities amounted to SEK -7.2 (-2.4) million. The main reason for the decrease compared to the same period prior year is that a debt to a supplier from other quarters within the year of 12.1 MSEK has been paid. Investments amounted to SEK 26.3 (11.9) million, whereof SEK 18.8 (12.4) million was invested in intangible assets and SEK 7.4 (1.0) million was invested in tangible assets. Cash and cash equivalents at the end of the quarter amounted to SEK 160.0 (187.1) million.

'Breakthrough Device Designation' granted by FDA for XHPS

XVIVO Perfusion has been granted 'Breakthrough Device Designation' from the U.S. Food and Drug Administration (FDA) for the XVIVO Heart Preservation System (XHPS), indicated for the hypo-thermic non-ischemic perfusion of excised donor hearts for preservation prior to transplant. The Breakthrough Device Designation is intended to expedite the development and prioritize the review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The overall goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

Australian subsidiary established

Based on the increasing interest for XVIVO Perfusion's products for lung transplantation as well as the high interest from all Australian clinics to participate in the Heart preservation study XVIVO Perfusion AB (publ) has decided to open a subsidiary in Sydney, Australia. XVIVO also recently hired a Regional Business Manager with start date in October 2019.

Warrants for employees, series 2019/2021, fully subscribed

XVIVO Perfusion issue of warrants for employees of series 2019/2021, with a total of 351 000 warrants is fully subscribed. The warrants may be exercised to subscribe for new shares at the share price of SEK 278.91 in May 2021.

THE PERIOD 2019 (JANUARY - DECEMBER)

Net Sales

Total net sales in the period amounted to SEK 220.8 (187.9) million, corresponding to an increase of 18 percent in SEK and 10 percent in local currency. Net sales of non-durable goods* in the period amounted to SEK 206,9 (172.7) million, corresponding to

an increase of 20 percent in SEK and 12 percent in local currency.

Total sales from warm perfusion (STEEN Solution™, XPS™, LS™, and products and services related to the use of the XPS™ and LS™) accounted for 48 (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 45 (43) percent of the total sales of non-durable goods.

Income

The gross margin for non-durable goods during the period was 77 (77) percent. The total gross margin during the period was 74 (72) percent. The increase is mainly attributable to changes in segment mix.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 28.8 (30.9) million, corresponding to an EBITDA margin of 13 (16) percent. The decrease in EBITDA margin compared to last year is mainly due to increased sales and R&D costs, caused by increased investments in to marketing and product development. During the period, costs for the share-based bonus program for employees outside Sweden amounted to SEK 7.0 (2.8) million. See note 2 for more information. EBITDA adjusted for costs for the share-based bonus program for employees outside Sweden amounted to SEK 35.8 million (33.7), corresponding to an EBITDA margin of 16 percent (18).

Operating income amounted to SEK 3.9 (14.0) million, after amortization and depreciation of SEK 24.9 (16.9) million. Adjusted operating income for the period was SEK 7.0 million (2.8).

Selling expenses in relation to sales during the period was 28 (26) percent. The increase is mainly due to a larger organization and investments into marketing. R&D expenses amounted to 28 (27) percent of sales. The increase of R&D expenses in relation to sales is primarily attributable to increased depreciations and the upgrade of the XPS-technology with the aim of supporting the growth within EVLP. Administration expenses was 11 (12) percent of sales. Net of other operating revenues and expenses during the period were SEK -10.7 (-3.6) million. The increase is explained by the share-based bonus program.

During the period, SEK 69,8 (47.2) millions of the development costs were capitalized as intangible assets. SEK 10.0 (19.0) million was attributable to the now finalized NOVEL study with STEEN Solution™ and XPS™ with the aim of PMA approval. The approval was received during the second quarter of 2019 and therefore it is fully capitalization. SEK 52,7 (26.9) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, SEK 4.2 (0.7) million was attributable to PrimECC and SEK 2.9 (0.6) million was attributable to product development of the rest of the

product portfolio. Amortization of capitalized development costs for the period amounted to SEK 13.7 (10.2) million, of which SEK 9.9 (9.9) million was amortization of the HDE approval and SEK 3.4 (-) million was amortization of the PMA approval.

Cash flow

Cash flow from operating activities amounted to SEK 29.5 (23.6) million. The increase comes from stronger operating cashflow, mainly affected by lower receivables on customers. Investments amounted to SEK 83.8 (53.2) million, whereof SEK 73.2 (48.0) million was invested in intangible assets and SEK 10.5 (6.7) million was invested in tangible assets and 0.1 in financial assets. The cash flow from financing activities was SEK 25.6 (19.2) million due to the issue of new shares related to a share warrant program and after amortization of leasing debts of SEK 3.3 million. Cash and cash equivalents at the end of the period amounted to SEK 160.0 (187.1) million.

Financing

XVIVO Perfusion's 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 was utilized. The equity/assets ratio was 91 (92) percent at the end of the period.

Perfadex® Plus has received patent approval in Europe

XVIVO Perfusion has received European patent approval for the company's ready to use product Perfadex® Plus for cold preservation of lungs. Perfadex® Plus was launched in Europe and the US in 2018. Patent applications for the new formulation have been submitted in all important markets.

XVIVO and MyCartis engage to develop a fast diagnostic test to assess the quality of donated organs before transplantation

During the third quarter, MyCartis and XVIVO Perfusion AB announced a collaboration to engage in the development of a fast diagnostic tool to timely assess the quality of donated organs during ex-vivo perfusion. Such test can guide the transplant surgeon and team on the quality of an organ and the chances of a positive outcome for the recipient. MyCartis is a Belgian company in the field of rapid diagnostics.

Currently, surgeons rely on physiological criteria to determine the fitness of an organ, whereas signs of non-fitness, like inflammation or tissue damage, may remain unnoticed by such means. Biomarker assessment to identify and quantify these unfavorable conditions in a timely manner would help the surgeon in the decision process. The MyCartis Evaluation™ platform is unique in its ability to measure multiple biomarkers simultaneously in a fast and easy way using a workflow that enables repeated testing. In a recent whitepaper, MyCartis demonstrated the successful application of interleukin-1β as an indicator for inflammation in lung organs during perfusion. With results generated within 20

minutes, this test meets the required turnaround time for real-time organ assessment as well as organ follow-up. MyCartis and XVIVO decided to expand the real-time testing panel to also enable the quantitation of organ damage next to the degree of inflammation. Both phenomena are negative indicators for successful transplantation.

Results from the heart preservation study presented on ISHLT

ISHLT (The International Society for Heart and Lung Transplantation) was held at the beginning of April. At the conference, Professor Johan Nilsson presented the positive results from the first six heart transplant patients from the ongoing study at Lund University Hospital. The results of the study indicate that the method is safe to use in humans. This means that larger randomized studies can be initiated with the heart preservation method. If the new method in larger studies demonstrates the same effect on humans as on animals, it will be possible to use significantly more donated hearts for transplantation. XVIVO Perfusion has, through its cooperation agreement with Igelösa Life Science, the commercial rights to Professor Stig Steen's research in heart transplantation.

Approximately 7,500 heart transplants are performed in the world each year and the limiting factor for more heart transplants are the lack of donated hearts and that the generally accepted maximum transport time today is about four hours. The new preservation method includes a machine that supplies the heart with important substances in an oxygenated solution (patent application submitted) before transplantation. In previous animal experiments using the new method, the preservation time for the donated heart has been significantly extended and the function of the donated heart has been better preserved.

XVIVO has received Premarket approval (PMA) from the FDA for STEEN Solution™ and XPS™

On April 26, 2019 XVIVO received Premarket approval (PMA) from the FDA for the products XPS™ and STEEN Solution™ for sale on the American market. The PMA approval was the first of its kind and means that more lung transplants are made possible without the limitations that the HDE approval entailed and that the clinics' reimbursement process is facilitated.

The process to receive market approval from the FDA began in 2009 and the company's HDE application was approved in August 2014. During the course of the process, clinical studies have been conducted to prove product and patient safety, and in March 2014, the FDA's expert panel unanimously voted that the XPS™ and STEEN Solution™ meets the requirements for HDE approval. An HDE approval involves certain limitations, including that a maximum of 8,000 patients may be treated per year and that separate ethical permits are required for treatment. With the PMA approval, the products can now be sold on the American market without such restrictions and will be labeled for warm perfusion of initially not accepted donated lungs.

XVIVO Perfusion will perform a Post Approval Study (PAS) required by the FDA to monitor the long-term results of EVLP through an official US registry comparing traditionally donated lungs to those where EVLPs have been performed prior to transplantation. Costs for the PAS study will be capitalized on an ongoing basis during the five years it is expected to last.

XVIVO's patents for the heart preservation fluid approved in the US and Europe

XVIVO's patents for the heart preservation fluid have been approved in the US and Europe. Canada has already approved this patent. XVIVO has also previously received a patent for the heart evaluation equipment in Europe, Australia, Canada and China. The review of the patent application for the heart evaluation equipment is in its final stages in the US. Together these patents strengthen XVIVO's position in the heart transplantation field on all major markets in the world.

XVIVO has two main patents in the field of heart transplantation. The first of these covers the preservation fluid that is used in heart preservation and the other covers important parts of the evaluation equipment that is to be used for heart evaluation after preservation, but before transplantation.

The Swedish MPA has given approval to begin clinical studies with the company's new products for heart preservation

XVIVO has received approval from the Swedish Medical Products Agency (MPA) to begin the clinical study with XVIVO's heart preservation products. Applications have been submitted to the other EU countries that will participate in the study. The study will form the basis for regulatory approval in Europe, known as the CE mark. The study will begin as soon as regulatory approvals and ethical approvals from hospital committees have been obtained.

The heart preservation study in Europe is a randomized study planned to include eight centers in seven European countries. The aim of the study is to clinically show that the technology is safe and improves the preservation of the donated heart during transport.

The company also plans to begin clinical trials in the US to obtain regulatory approvals as well as in Australia to expand the documentation of the cardiac preservation products. The products for heart preservation consist of a portable machine with associated sterile disposable products, as well as a patented innovative solution that perfuse, and oxygenate, the heart during transportation and preservation. The technology is developed by Professor Stig Steen at Igelösa Life Science and it is a task that started approximately ten years ago. Over the past two years, XVIVO has further developed the products and setup large-scale production of the heart preservation fluid.

Reimbursement for the entire EVLP process obtained in France

Reimbursement for the EVLP process obtained in France. This means that clinics in France not only receive compensation for the EVLP kits used at an EVLP but also receive reimbursement for the clinical team's time during an EVLP.

SEK 27 million share issue because of warrants being exercised

Because of warrants being exercised, the number of shares and votes in XVIVO Perfusion AB (publ) has during the period increased by 198.000 shares and votes. As of December 31, 2019, there were a total of 26,600,496 shares and votes in the company. The share issue of 198.000 shares raised approximately SEK 27 million.

OUTLOOK 2020

As the number of lungs that can be transplanted using traditional cold preservation is not expected to increase more than the number of donated lungs in existing markets in North America and Europe, growth in these markets is expected to come primarily from evaluation using warm perfusion of lungs. Emerging markets, such as China and India where the capacity for lung transplantations is being expanded, are expected to display higher growth for both EVLP and traditional cold preservation using Perfadex® Plus. The focus during 2020 is therefore on continuing to develop the market for STEEN Solution™, with the objective to become the standard treatment in the transplantation of lungs in addition to increasing the company's investments in emerging markets to assure sustainable global growth moving ahead.

The company will intensify its research and development in the field of heart transplantation, with the aim of starting clinical multi-center studies in Europe, the US and Australia which will form the basis of regulatory approval. Expenditure attributable to the development of heart transplantation will be capitalized on an ongoing basis.

In regard to research and development, the company will carry out work with the aim of expanding the use of the STEEN Solution™ method for other organs. In addition, the company will continue to develop other areas of use for the company's solution technology including warm perfusion of organs that are still in the body and the priming of heart-lung machines. An example of the latter is PrimECC®, a patented product that has been approved in Europe for the priming of heart-lung machines before open heart surgery. PrimECC® has been developed with an objective to decreasing the adverse effects when using this type of device. The company plans to increase the documentation of PrimECC® during 2020 by performing multicenter studies. Expenditure attributable to documentation of PrimECC® will be capitalized on an ongoing basis up until market launch.

THE COMPANY IN BRIEF

Operations

XVIVO Perfusion AB is a medical technology company which develops solutions and systems for selecting usable organs and maintaining them in optimal condition pending transplantation. 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 life saving 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 2019, the number of employees was 53, of whom 23 were women and 30 were men. Of these, 30 people were employed in Sweden and 23 outside Sweden. In addition, the company uses around 10 consultants.

Information on transactions with related parties

During the financial year, one transaction with the Board member Folke Nilsson has been conducted amounting to SEK 93 thousand.

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 2018 annual report.

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.

Nomination Committee for the 2020 Annual General Meeting

The following members have been appointed to XVIVO Perfusion's Nomination Committee for the 2020 Annual General Meeting:

Henrik Blomquist, appointed by Bure Equity AB
Martin Lewin, appointed by Eccenovo AB
Joachim Spetz, appointed by Swedbank Robur
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 28 percent of the votes attached to all voting shares in the company.

Annual General Meeting and Annual Report

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on 31 Mars, 2020 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 2019 will be available for download on XVIVO Perfusion's website during the week commencing Monday, March 9.

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 half-year 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 face

Gothenburg
January 30, 2020

Magnus Nilsson
CEO

Gösta Johannesson
Chairman of the Board

Camilla Öberg
Board member

Folke Nilsson
Board member

Yvonne Mårtensson
Board member

Alan Raffensperger
Board member

Dag Andersson
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. Following reports are planned to be submitted:

Interim Report January-March 2020: Friday, April 17, 2020
Interim Report January-June 2020: Friday, July 10, 2020
Interim Report January-September 2020: Friday, October 23, 2020
Report on Operations 2020: Thursday, January 28, 2021

For further information, please contact

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magnus.nilsson@xvivoperfusion.com
Christoffer Rosenblad, CFO, +46 735 192159,
christoffer.rosenblad@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 30, 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

SEKTHOUSANDS	January – December		October – December	
	2019	2018	2019	2018
Net sales	220 837	187 868	62 416	58 389
Cost of goods sold	-58 024	-51 915	-16 710	-16 615
Gross income	162 813	135 953	45 706	41 774
Selling expenses	-60 786	-47 948	-18 372	-14 166
Administrative expenses	-24 739	-22 519	-7 152	-7 808
Research and development costs	-62 651	-47 931	-17 964	-12 560
Other operating revenues and expenses*	-10 697	-3 555	-622	-1 126
Operating income	3 940	14 000	1 596	6 114
Financial income and expenses	1 350	3 498	-3 838	1 208
Income after financial items	5 290	17 498	-2 242	7 322
Taxes	-351	-4 813	340	-2 437
Net income	4 939	12 685	-1 902	4 885
Attributable to				
Parent Company's shareholders	4 939	12 685	-1 902	4 885
Earnings per share, SEK	0,19	0,48	-0,07	0,19
Earnings per share, SEK**	0,19	0,48	-0,07	0,19
Average number of outstanding shares	26 518 546	26 302 385	26 600 496	26 402 496
Average number of outstanding shares**	26 799 996	26 302 385	26 879 496	26 402 496
Number of shares at closing day	26 600 496	26 402 496	26 600 496	26 402 496
Number of shares at closing day**	26 879 496	26 402 496	26 879 496	26 402 496
EBITDA	28 800	30 923	8 479	10 485
Amortization	-14 539	-10 861	-4 107	-2 725
Depreciation	-10 321	-6 062	-2 776	-1 646
Operating income	3 940	14 000	1 596	6 114

* Item "Other operation revenues and expenses" for 2019 includes costs for a share based bonus program for employees based outside of Sweden. Accumulated for the period January-December 2019, the cost amounted to SEK -7 046 thousand (-2 800). During the fourth quarter the cost was positive of SEK 237 thousand (812) due to resolution of a provision. During 2018 the cost was recognized in the respective function. See note 2 for more information.

** After dilution. See note 2 for information on warrant programs.

CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME

SEKTHOUSANDS	January – December		October – December	
	2019	2018	2019	2018
Net income	4 939	12 685	-1 823	4 885
Other comprehensive income				
<i>Items that may be reclassified to the income statement</i>				
Exchange rate differences	3 721	4 875	-3 691	1 126
Tax attributable to items that have been transferred, or can be transferred to net income	-514	-473	343	-164
Total other comprehensive income, net after tax	3 207	4 402	-3 348	962
Total comprehensive income	8 146	17 087	-5 250	5 847
Attributable to				
Parent Company's shareholders	8 146	17 087	-5 250	5 847

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK THOUSANDS	Dec 31, 2019	Dec 31, 2018
ASSETS		
Goodwill	65 773	65 614
Capitalized development expenditure	266 517	210 460
Other intangible fixed assets	6 219	3 624
Fixed assets	23 554	15 615
Financial assets	12 539	13 619
Total non-current assets	374 602	308 932
Inventories	43 871	36 387
Current receivables	56 068	54 229
Liquid funds	159 946	187 064
Total current assets	259 885	277 680
Total assets	634 487	586 612
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity, attributable to the Parent Company's shareholders	577 521	540 477
Long-term interest-bearing liabilities	2 154	-
Long-term non-interest-bearing liabilities	2 213	3 562
Short-term interest-bearing liabilities	3 396	-
Short-term non-interest-bearing liabilities	49 203	42 573
Total shareholders' equity and liabilities	634 487	586 612

CONSOLIDATED KEY RATIOS

	January – December		October – December	
	2019	2018	2019	2018
Gross margin non-Durable goods, %	77	77	77	78
Gross margin, %	74	72	73	72
EBITDA, %	13	16	14	18
Operating margin, %	2	7	3	10
Net margin, %	2	7	-3	8
Equity/assets ratio, %	91	92	91	92
Income per share, SEK	0,19	0,48	-0,07	0,19
Shareholders' equity per share, SEK	21,71	20,47	21,71	20,47
Share price on closing day, SEK	170,00	132,00	170,00	132,00

See page 17-18 for key ratios definition and reconciliation of alternative key figures.

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEKTHOUSANDS	January – December		October – December	
	2019	2018	2019	2018
Income after financial items	5 290	17 497	-2 241	7 321
Adjustment for items not affecting cash flow	28 862	15 263	12 722	1 739
Paid taxes	-2 945	628	-182	1 032
Change in inventories	-8 478	-2 311	1 892	102
Change in trade receivables	-542	-17 236	-6 292	-17 871
Change in trade payables	7 318	9 786	-13 117	5 304
Cash flow from operating activities	29 505	23 627	-7 218	-2 373
Cash flow from investing activities	-83 844	-53 198	-26 341	-11 910
Cash flow from financing activities	25 551	19 204	-686	0
Cash flow for the period	-28 788	-10 367	-34 245	-14 283
Liquid funds at beginning of period	187 064	195 322	197 643	201 248
Exchange rate difference in liquid funds	1 670	2 109	-3 452	99
Liquid funds at end of period	159 946	187 064	159 946	187 064

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, 2018	670	467 661	8 618	27 237	504 186
Total comprehensive income Jan - Dec, 2018			4 402	12 685	17 087
Share warrant program	5	19 017			19 022
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax		182			182
Shareholders' equity as of 31 december, 2018	675	486 860	13 020	39 922	540 477
Total comprehensive income January - Dec, 2019			3 207	4 969	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

CONDENSED CONSOLIDATED STATEMENT OF NET INCOME PER QUARTER

SEKTHOUSANDS	Oct - Dec 2019	Jul - Sep 2019	Apr - Jun 2019	Jan - Mar 2019	Oct - Dec 2018	Jul - Sep 2018	Apr - Jun 2018	Jan - Mar 2018
Net sales	62 416	54 334	56 437	47 650	58 389	40 914	46 090	42 475
Cost of goods sold	-16 710	-15 791	-14 789	-10 734	-16 615	-9 876	-13 061	-12 363
Gross income	45 706	38 543	41 648	36 916	41 774	31 038	33 029	30 112
Selling expenses	-18 372	-14 376	-15 957	-12 081	-14 166	-11 846	-11 549	-10 387
Administrative expenses	-7 152	-6 029	-6 148	-5 410	-7 808	-5 513	-4 684	-4 514
Research and development costs	-17 964	-16 827	-12 898	-14 962	-12 560	-11 734	-12 100	-11 537
Other operating revenues and expenses*	-622	966	-4 716	-6 325	-1 126	-1 207	-697	-525
Operating income	1 596	2 277	1 929	-1 862	6 114	738	3 999	3 149
Financial income and expenses	-3 838	3 210	527	1 451	1 208	-803	1 315	1 778
Income after financial items	-2 242	5 487	2 456	-411	7 322	-65	5 314	4 927
Taxes	340	-558	-229	96	-2 437	164	-1 420	-1 120
Net income	-1 902	4 929	2 227	-315	4 885	99	3 894	3 807
Attributable to								
Parent Company's shareholders	-1 823	4 929	2 227	-315	4 885	99	3 894	3 807
Earnings per share, SEK	-0,07	0,19	0,08	-0,01	0,19	0,00	0,15	0,15
Earnings per share, SEK**	-0,07	0,18	0,08	-0,01	0,19	0,00	0,15	0,15
Average number of outstanding shares	26 600 496	26 600 496	26 532 296	26 402 496	26 402 496	26 402 496	26 378 940	26 190 496
Average number of outstanding shares**	26 879 496	26 879 496	26 879 496	26 720 496	26 402 496	26 786 496	26 378 940	26 190 496
Number of shares at closing day	26 600 496	26 600 496	26 600 496	26 402 496	26 402 496	26 402 496	26 402 496	26 190 496
Number of shares at closing day**	26 879 496	26 879 496	26 879 496	26 879 496	26 402 496	26 879 496	26 402 496	26 190 496
EBITDA	8 479	9 025	8 055	3 241	10 485	5 207	8 075	7 156
Amortization	-4 107	-4 099	-3 618	-2 715	-2 725	-2 736	-2 699	-2 701
Depreciation	-2 776	-2 649	-2 508	-2 388	-1 646	-1 733	-1 377	-1 306
Operating income	1 596	2 277	1 929	-1 862	6 114	738	3 999	3 149

* Item "Other operation revenues and expenses" for 2019 includes cost for share based bonus program for employees based outside of Sweden. For the years in comparison the cost was reported in each function. During the fourth quarter the cost was positive of SEK 237 thousand (812) due to resolution of a provision. During the third quarter 2019 the cost amounted to thousand SEK 2 253 (-812), during the second quarter 2019 the cost amounted to SEK -4 000 (-2 800) and during the first quarter -5 536 TSEK (-). See note 2 for more information.

** After dilution. See note 2 for information on warrant programs.

CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME PER QUARTER

SEKTHOUSANDS	Oct - Dec 2019	Jul - Sep 2019	Apr - Jun 2019	Jan - Mar 2019	Oct - Dec 2018	Jul - Sep 2018	Apr - Jun 2018	Jan - Mar 2018
Net income	-1 902	4 929	2 227	-315	4 885	99	3 894	3 807
Other comprehensive income <i>Items that may be reclassified to the income statement</i>								
Exchange rate differences	-3 691	4 531	30	2 851	1 126	-801	4 413	137
Tax attributable to items that have been transferred, or can be transferred to net income	343	-487	-20	-350	-164	81	-466	76
Total other comprehensive income, net after tax	-3 348	4 044	10	2 501	962	-720	3 947	213
Total comprehensive income	-5 250	8 973	2 237	2 186	5 847	-621	7 841	4 020
Attributable to								
Parent Company's shareholders	-5 250	8 973	2 237	2 186	5 847	-621	7 841	4 020

CONDENSED INCOME STATEMENT FOR THE PARENT COMPANY

SEK THOUSANDS	January – December		October – December	
	2019	2018	2019	2018
Net sales	169 608	152 332	47 737	40 997
Cost of goods sold	-50 677	-39 735	-17 514	-10 941
Gross income	118 931	112 597	30 223	30 056
Selling expenses	-36 502	-27 940	-9 915	-8 395
Administrative expenses	-18 485	-12 578	-6 596	-5 000
Research and development costs	-65 937	-46 074	-16 291	-12 262
Other operating revenues and expenses	-181	-2 643	2 980	-704
Operating income	-2 174	23 362	401	3 695
Financial income and expenses	4 774	6 460	-5 066	2 176
Income after financial items	2 600	29 822	-4 665	5 871
Year end dispositions	-2 300	-19 537	-	-19 537
Taxes	-299	-2 487	83	2 954
Net income	1	7 798	-4 582	-10 712

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 17 832 (14 053) thousand, of which SEK 4 991 thousand (3 467) for the quarter.

CONDENSED BALANCE SHEET FOR THE PARENT COMPANY

SEK THOUSANDS	Dec 31, 2019	Dec 31, 2018
ASSETS		
Intangible fixed assets	206 205	149 153
Fixed assets	7 924	7 367
Financial assets	194 166	200 222
Total non-current assets	408 295	356 742
Inventories	15 070	14 360
Current receivables	34 352	27 687
Cash and bank	150 362	178 248
Total current assets	199 784	220 295
Total assets	608 079	577 037
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity	548 150	519 247
Untaxed reserves	4 200	10 150
Provisions	6 734	1 329
Short-term non-interest-bearing liabilities	48 995	46 311
Total shareholders' equity and liabilities	608 079	577 037

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. During 2019 the Group has started to apply IFRS 16 Leases. Effects of the transition is presented below.

IFRS 16 Leases

As of January 1, 2019, the Group applies IFRS 16 Leases. The new standard replaces previous IFRS related to the recognition of leasing agreements such as IAS 17 "Leases" and IFRIC 4 "Determining whether an agreement contains a lease". For the Group, the new standard means that "right of use" agreements for premises and equipment are recognised as an asset in the balance sheet and that a leasing debt is recognised, which represents an obligation to pay future leasing fees. Exemptions are used, which means that short-term leases and leases of low value are not capitalized. Instead they are expensed in the period of consumption. The parent company does not apply IFRS 16, in accordance with the exemptions stated in RFR 2.

A modified retrospective approach of IFRS 16 has been adopted, which has entailed effects on the balance sheet as of January 1, 2019. Comparative figures for previous periods have not been restated. As of January 1, 2019, an tangible asset of TSEK 8.727 have been recognized. The corresponding amount has been recognized as current lease debt, TSEK 3.363, and long-term lease debt, TSEK 5.364. Total leasing debt as of January 1, 2019 thus amounts to SEK 8.727 thousand, which is to be compared with the information in the most recently prepared annual report for 2018, where future operational lease commitments are stated to amount to SEK 8.500 thousand. The difference is due to discounting effects and additional reasonably safe extension periods. An average marginal loan rate of 2.3 percent has been used in the calculations.

At the end of the period, December 31, 2019, the Group reports the following book values of leased assets: Tangible assets SEK 5 550 (-) thousand. The effect of IFRS 16 in the consolidated income statement for the period January-December, 2019, is that depreciation of SEK 3.349 thousand and interest expense of SEK 161 thousand replaced operating leasing cost of SEK 3.510 thousand. The new standard has therefore not had any effect on the net result for the period, compared with if IAS 17 was applied.

Note 2. Share warrant programs

In total there are 579.000 outstanding warrants in two programs. The Annual General Meeting of 2018 resolved to issue no more than 315.000 warrants (series 2018/2020), with the right to subscribe a maximum of 315.000 new shares to employees of the XVIVO Perfusion Group. As per June 30, 2019, 279.000 of these warrants have been subscribed for. Each warrant entitles the holder to subscribe for a new share in May 2020, at a price of SEK 146.02.

The Annual General Meeting of 2019 resolved to issue no more than 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. As per December 31, 2019, all 351.000 warrants have been subscribed for. Each warrant entitles the holder to subscribe for a new share in May 2021, at a price of SEK 278.91.

During the period January-December 2019, both the average share price for the period and the closing price at period end exceeded the exercise price of warrant program series 2018/2020, whereby the warrant program at strike is expected to result in a total dilution effect for existing shares of approximately 1.0 percent.

The Annual General Meeting in 2018 and 2019 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.

Note 3. Financial data per segment, Group

SEK Thousands	January - December		Durable goods		Total consolidated	
	Net sales of non-Durable goods		2019	2018	2019	2018
	2019	2018				
Net sales	206 857	172 693	13 980	15 175	220 837	187 868
Cost of goods sold	-47 439	-39 406	-10 585	-12 509	-58 024	-51 915
Gross income	159 418	133 287	3 395	2 666	162 813	135 953

SEK Thousands	October - December		Durable goods		Total consolidated	
	Net sales of non-Durable goods		2019	2018	2019	2018
	2019	2018				
Net sales	59 401	52 333	3 015	6 056	62 416	58 389
Cost of goods sold	-13 771	-11 521	-2 939	-5 094	-16 710	-16 615
Gross income	45 630	40 812	76	962	45 706	41 774

Note 4. Financial instruments

The Group's financial assets and liabilities valued at acquisition value amount to SEK 216 (241) million and SEK 49 (34) million respectively. Fair value of the Group's financial assets and liabilities is assessed to correspond to the book value.

RECONCILIATION OF ALTERNATIVE KEY FIGURES

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	January - December		October - December	
	2019	2018	2019	2018
Operating income	3 940	14 000	1 596	6 114
Amortization	14 539	10 861	4 107	2 725
Depreciation	10 321	6 062	2 776	1 646
EBITDA	28 800	30 923	8 479	10 485

Gross margin

SEK THOUSANDS	January - December		October - December	
	2019	2018	2019	2018
Operating income				
Net sales	220 837	187 868	62 416	58 389
Operating expenses				
Cost of goods sold	-58 024	-51 915	-16 710	-16 615
Gross income	162 813	135 953	45 706	41 774
Gross margin %	74	72	73	72

Gross margin non-Durable goods

SEK THOUSANDS	January - December 2019	December 2018	October - December 2019	December 2018
Operating income				
Net sales of non-Durable goods	206 857	172 693	59 401	52 333
Operating expenses				
Cost of non-Durable goods sold	-47 439	-39 406	-13 771	-11 521
Gross income, non-Durable goods	159 418	133 287	45 630	40 812
Gross margin, non-Durable goods %	77	77	77	78

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	December 31, 2019	December 31, 2018
Shareholders' equity	577 521	540 477
Total assets	634 487	586 612
Equity/assets ratio %	91	92

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

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.

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).

XVIVO PERFUSION'S PRODUCTS

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



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