



# INTERIM REPORT

## JANUARY-SEPTEMBER 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, XPST™ 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.*



# GOOD GROWTH AND NEW IMPORTANT XPS CLINICS

## THIRD QUARTER 2019 (JUL - SEP)

- Net sales of non-durable goods\* in the quarter amounted to SEK 50.1 (40.3) million, corresponding to an increase of 25 percent in SEK and 18 percent in local currency. Total net sales (incl. durable goods) in the quarter amounted to SEK 54.3 (40.9) million, corresponding to an increase of 33 percent in SEK and 26 percent in local currency.
- Sales from warm perfusion\*\* represented 42 percent (40) 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 6.8 million (6.0), corresponding to an EBITDA margin of 13 percent (15). Reported EBITDA amounted to SEK 9.0 (5.2) million, corresponding to an EBITDA margin of 17 percent (13).
- Operating income adjusted for the share-based bonus program was SEK 0.0 million (1.6). Reported operating income amounted to SEK 2.3 (0.7) million, after amortization and depreciation of SEK 6.7 (4.5) million.
- Net income amounted to SEK 4.9 (0.1) million, resulting in earnings per share of SEK 0.19 SEK (0.00).
- Cash flow from operating activities during the quarter amounted to SEK 15.6 (3.7) million. Cash flow from investing activities amounted to SEK -18.0 (-11.3) million.
- XPS™ sold to Chinas second largest clinic for lung transplantation.
- Lung Bioengineering has acquired the XPS™ for use in its new EVLP center in Jacksonville, Florida, USA.
- Perfadex® Plus received patent approval in Europe
- XVIVO and MyCartis engage to develop a fast diagnostic test to assess the quality of donated organs before transplantation.

## THE PERIOD 2019 (JAN - SEP)

- Net sales of non-durable goods\* in the period amounted to SEK 147,5 (120,4) million, corresponding to an increase of 23 percent in SEK and 15 percent in local currency. Total net sales (incl. durable goods) in the period amounted to SEK 158,4 (129,5) million, corresponding to an increase of 22 percent in SEK and 14 percent in local currency.
- Sales from warm perfusion\*\* represented 43 percent (40) 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 27.6 million (24.0), corresponding to an EBITDA margin of 17 percent (19). Reported EBITDA amounted to SEK 20.3 (20.4) million, corresponding to an EBITDA margin of 13 percent (16).
- Operating income adjusted for the share-based bonus program was SEK 9.6 million (11.5). Reported operating income amounted to SEK 2.3 (7.9) million, after amortization and depreciation of SEK 18.0 (12.6) million.
- Net income amounted to SEK 6.8 (7.8) million, resulting in earnings per share of SEK 0.26 (0.30).
- Cash flow from operating activities for the period amounted to SEK 36.7 (26.0) million. Cash flow from investing activities amounted to SEK -57.5 (-41.3) 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.
- 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'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.
- SEK 27 million shares was issued because of warrants being exercised.
- 4 XPS™ were delivered during the period. At the end of the period 50 hospitals had access to either XPS™ or LS™. During the period, Canada became a new country with XPS™.

## EVENTS AFTER THE PERIOD

- XVIVO has decided to establish an Australian wholly owned subsidiary during the fourth quarter
- The company's warrants program (series 2019/2021) has been closed. All of the 351,000 warrants were subscribed. The warrants give the holder the right to subscribe for a new share in May 2021 at a price of SEK 278.91.

## MILESTONES PASSED DURING THE QUARTER

XPS™ sold to China's second largest clinic for lung transplantation

Perfadex® Plus received patent approval in Europe

Lung Bioengineering has acquired the XPS™ for use in its new EVLP center in Jacksonville, Florida, USA.

XVIVO and MyCartis started a collaboration developing a fast diagnostic test with use of biomarkers

## CEO'S COMMENTS



As the year has proceeded XVIVO Perfusion's sales have developed strongly and the product development projects have been conducted at an intense pace. These positive developments have resulted in yet another positive quarter for the company. This good rate of quarter on quarter growth, while maintain-

ing a good gross margin, has resulted in positive EBITDA and strong cash flow. This has enabled us to continue to invest in expanding our marketing organization in addition to our product development capacity.

XVIVO Perfusion's market launch of products for lung transplantation is proceeding successfully. Growth of sales of non-durable goods during the third quarter was +18 percent in local currency. The launch of Perfadex® Plus, the company's new ready-to-use product for the preservation of lungs, is going according to plan in Europe and the US. The patent approvals for Perfadex® Plus are important to retain the company's high market share in this growing market. There is an ongoing dialogue with regulatory authorities in the rest of the world with an aim to launch Perfadex® Plus outside the US and Europe as soon as regulatory approval has been attained in these markets. Two important XPS™ sales were made during the quarter. The first sale is to the Lung Bioengineering's (United Therapeutics' subsidiary) newly inaugurated second EVLP center located in Jacksonville, Florida. The second XPS™ sale is to China's second largest lung transplantation clinic located in Beijing. The Beijing center is also the fastest growing in China. The number of lung transplantations is increasing rapidly in China and it is anticipated that in 2-3 years the country will be amongst the largest markets in the world.

Work is proceeding at full steam with the preparations to start up multicenter studies on the company's product for heart preservation in Europe (seven countries, eight centers) including the US in addition to Australia-New Zealand. The time when these studies will be carried out is highly dependent on when approval can be obtained from authorities and hospital committees for all the centers in the studies. Clinics have continued to show very great interest in participating.

The regulatory file for the new version of PrimECC® production in environmentally friendly packaging was submitted during the quarter. The regulatory review of this change still lies ahead. Once the regulatory review has been completed the next stage of clinical development can be initiated. Given the planned change in the EU regulations for medical device products which will begin to be implemented shortly the so-called "Notified Bodies" currently have a very heavy workload. This increase in workload has unfortunately entailed slightly longer review times.

XVIVO Perfusion's focus for the lung transplantation area is to continue expanding the installation base of the company's EVLP machines, above all in Europe and in the new markets, in addition to continuing to refine and simplify the EVLP technology. This is behind our mission to support the transplantation surgeons in their efforts to be able to treat more of the patients on the transplantation waiting lists. In the field of heart transplantation, our focus is on working to gain authority approval for all centers in the multicenter studies with the EU study being first in line. In general terms, XVIVO's research focuses on continuing to lead the development of innovative solutions in the field of thorax transplantation in addition to applying the company's experience and knowledge to the development of perfusion for abdominal organs as well.

Magnus Nilsson  
CEO

## CONFERENCE CALL

CEO Magnus Nilsson will present the report in a conference call at 2 p.m. CET on Thursday, October 24, 2019. Telephone UK: +44 333 300 0804 or USA: +1 631 913 1422. PIN: 12283129#

## THIRD QUARTER 2019 (JULY - SEPTEMBER)

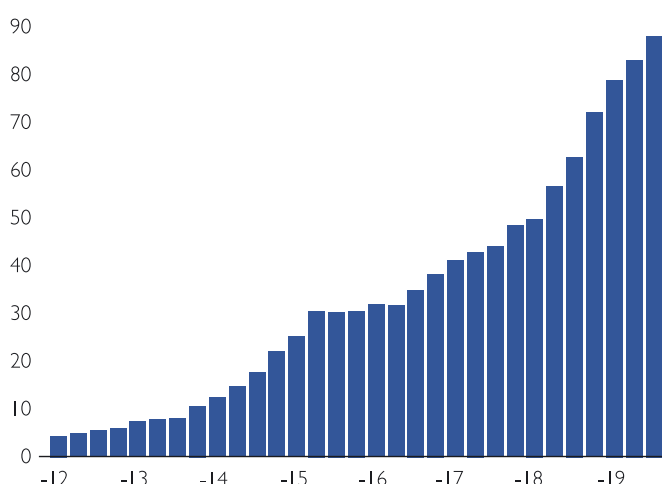
### Net Sales

Total net sales in the quarter amounted to SEK 54.3 (40.9) million, corresponding to an increase of 33 percent in SEK and 26 percent in local currency. Net sales of non-durable goods\* in

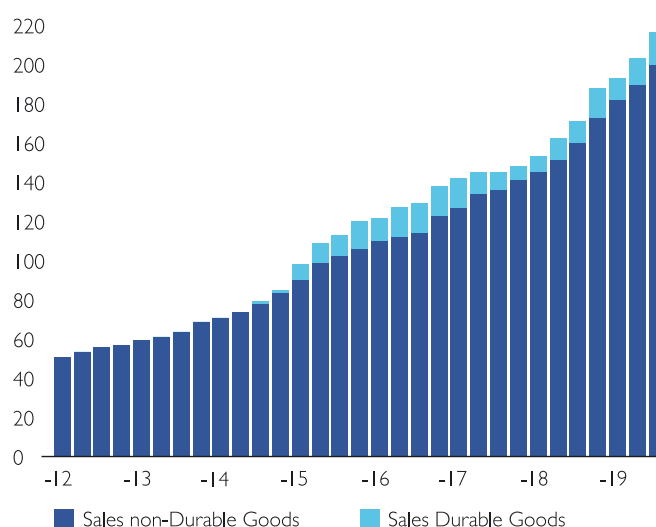
the quarter amounted to SEK 50.1 (40.3) million, corresponding to an increase of 25 percent in SEK and 18 percent in local currency.

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 46 (41) percent of the total sales. Warm perfusion sales from non-durable

**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 - September 2019	January - September 2018	July - September 2019	July - September 2018	Whole year 2018
Net Sales non-Durable Goods	147 456	120 360	50 137	40 251	172 693
Net Sales Durable Goods	10 965	9 119	4 197	663	15 175
<b>Net Sales Total</b>	<b>158 421</b>	<b>129 479</b>	<b>54 334</b>	<b>40 914</b>	<b>187 868</b>
Cost of Goods non-Durable Goods	-33 668	-27 885	-11 677	-9 413	-39 406
Cost of Goods Durable goods	-7 646	-7 415	-4 114	-463	-12 509
Cost of Goods Total	-41 314	-35 300	-15 791	-9 876	-51 915
Gross income non-Durable Goods	113 788	92 475	38 460	30 838	133 287
Gross margin non-Durable Goods, %	77%	77%	77%	77%	77%
Gross income Durable Goods	3 319	1 704	83	200	2 666
Gross income Total	117 107	94 179	38 543	31 038	135 953
Gross margin Total, %	74%	73%	71%	76%	72%
Selling expenses	-42 414	-33 782	-14 376	-11 846	-47 948
Administrative expenses	-17 587	-14 711	-6 029	-5 513	-22 519
Research and development costs	-44 687	-35 371	-16 827	-11 734	-47 931
Other operating revenues and expenses**	-10 075	-2 429	966	-1 207	-3 555
<b>Operating Income</b>	<b>2 344</b>	<b>7 886</b>	<b>2 277</b>	<b>738</b>	<b>14 000</b>
Depreciation of cost of goods sold	-607	-350	-208	-151	-527
Depreciation of administrative expenses	-1 585	-1 036	-628	-502	-1 384
Amortization of research and development expenses	-11 931	-8 163	-4 697	-2 749	-10 900
Depreciation of other operative expenses	-3 854	-3 003	-1 215	-1 067	-4 112
<b>EBITDA</b>	<b>20 321</b>	<b>20 438</b>	<b>9 025</b>	<b>5 207</b>	<b>30 923</b>
EBITDA, %	13%	16%	17%	13%	16%

\*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-September 2019, the cost amounted to SEK -7 283 thousand (-3 612). During the third quarter the cost was positive of SEK 2 253 thousand (-812) due to resolution of a provision. During 2018 this cost was recognized in the respective functions.

goods (STEEN Solution™, products and services related to the use of the XPS™ and LS™) accounted for 41 (40) percent of the total sales of non-durable goods.

### Income

The gross margin for non-durable goods during the quarter was 77 (77) percent. The total gross margin during the quarter was 71 (76) percent.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 9.0 (5.2) million, corresponding to an EBITDA margin of 17 percent (13). During the third quarter, costs for the share-based bonus program for employees outside Sweden was positive, SEK 2.3 million, due to a resolution of an earlier made provision. EBITDA adjusted for costs for the share-based bonus program for employees outside Sweden amounted to SEK 6.8 million (6.0), corresponding to an EBITDA margin of 13 percent (15).

Operating income amounted to SEK 2.3 (0.7) million, after amortization and depreciation of SEK 6.7 (4.5) million. Adjusted operating income for the quarter was SEK 0.0 million (1.6).

Selling expenses in relation to total sales during the quarter was 26 (29) percent. When excluding sales from capital goods for the quarter, the relation is in line with last year. R&D expenses amounted to 31 (29) percent of sales. Administration expenses was 11 (13) percent of sales. Net of other operating revenues and expenses during the quarter were SEK 1 (-1.2) million.

During the quarter, SEK 15.6 (10.3) million of the development costs were capitalized as an intangible asset. SEK 14.7 (6.6) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, SEK 0.5 million (0.0) was attributable to PrimeCC and SEK 0.4 (3.7) 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 1.3 (-) million was amortization of the PMA approval.

### Cash flow

Cash flow from operating activities during the quarter amounted to SEK 15.6 (3.7) million. The increase is explained primarily of an increased EBITDA adjusted for share-based bonus program, but also due to withholding payments of SEK 3.8 million to a supplier because of inaccurate VAT charging from the supplier. The amount will be paid during the fourth quarter and then have a negative impact on the cash flow. Cash flow from investment activities amounted to SEK -18.0 (-11.3) million, whereof SEK -16.7 (-10.3) million was invested in intangible assets and SEK -1.3 (-1.0) million was invested in tangible assets. Cash and cash equivalents at the end of the quarter amounted to SEK 197.6 (201.3) million.

### XPS™ sold to China

XVIVO Perfusion has sold an XPS™ to the second largest lung transplant clinic in China, the China-Japan Friendship Hospital, in Beijing. China currently shows the fastest growth in the world with a 35 percent increase in lung transplants in 2018 (403 lung transplants performed). Due to the increased need for lung transplantation the number of clinics authorized to perform lung transplants has increased from 20 clinics in 2016 to 37 clinics in 2018.

The lung transplant program lead by Professor Jingyu Chen will head the EVLP program at the China-Japan Friendship Hospital in Beijing. They will investigate the effects of EVLP on Lung transplantation. XVIVO Perfusion has initiated a registration process of the XPS™ with the NMPA, the Chinese regulatory authority. In partnership with XVIVO Perfusion's Distributor in China (Shanghai Genext Medical Technology Co., Ltd), the company plan to scientifically support the Lung transplant clinic of China-Japan Friendship Hospital in Beijing.

### Lung Bioengineering has acquired the XPS™ for use in its new EVLP center in Jacksonville

Lung Bioengineering Inc., a subsidiary of United Therapeutics Corporation, has purchased an XVIVO Perfusion System (XPS™) with STEEN Solution™ Perfusate to use in its new ex vivo lung perfusion (EVLP) center in Jacksonville, Florida. Lung Bioengineering previously purchased an XPS™ to use in its EVLP center in Silver Spring, Maryland in 2018. The aim of these EVLP centers is to reduce the shortage of transplantable lungs through the use of a centralized organ evaluation service. XVIVO Perfusion will continue to provide training and supplies for use of their machines by transplant hospitals to re-evaluate donated lungs that have initially been deemed unsuitable for transplant.

### 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.

As XVIVO Perfusion has previously reported, the company has developed a new ready to use version of its product for cold preservation of lungs. Patent applications for the new formulation, which is called Perfadex® Plus, have been submitted in all important markets and the European patent authority has now approved the patent in Europe. Perfadex® Plus was launched in the principal markets, the US and Europe, in 2018 and the work on regulatory approval for Perfadex® Plus is ongoing, with the aim that the product is approved in all markets in 2019.

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

During the 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-1 $\beta$  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.

## **THE PERIOD 2019 (JANUARY - SEPTEMBER)**

### **Net Sales**

Total net sales in the period amounted to SEK 158.4 (129.5) million, corresponding to an increase of 22 percent in SEK and 14 percent in local currency. Net sales of non-durable goods\* in the period amounted to SEK 147.5 (120.4) million, corresponding to an increase of 23 percent in SEK and 15 percent in local currency.

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 47 (44) 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 43 (40) 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 (73) percent. The increase is mainly attributable to changes in segment mix.

Operating income before depreciation and amortization

(EBITDA) amounted to SEK 20.3 (20.4) million, corresponding to an EBITDA margin of 13 percent (16). During the period, costs for the share-based bonus program for employees outside Sweden amounted to SEK 7.3 (3.6) million. See note 2 for more information. EBITDA adjusted for costs for the share-based bonus program for employees outside Sweden amounted to SEK 27.6 million (24.0), corresponding to an EBITDA margin of 17 percent (19).

Operating income amounted to SEK 2.3 (7.9) million, after amortization and depreciation of SEK 18.0 (12.6) million. Adjusted operating income for the period was SEK 9.6 million (11.5).

Selling expenses in relation to sales during the period was 27 (26) percent. R&D expenses amounted to 28 (27) percent of sales. Administration expenses was 11 (11) percent of sales. Net of other operating revenues and expenses during the period were SEK -10.1 (-2.4) million. Of this increase, SEK 7.3 million is explained by the share-based bonus program.

During the period, SEK 52.2 (35.1) million of the development costs were capitalized as an intangible asset. SEK 10.0 (16.2) million was attributable to the now finalized NOVEL study with STEEN Solution™ and XPS™ with the aim of PMA approval. SEK 38.3 (18.3) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, SEK 2.1 (0.2) million was attributable to PrimECC and SEK 1.8 (0.4) million was attributable to product development of the rest of the product portfolio. Amortization of capitalized development costs for the period amounted to SEK 9.8 (7.6) million, of which SEK 7.5 (7.5) million was amortization of the HDE approval and SEK 2.3 (-) million was amortization of the PMA approval.

### **Cash flow**

Cash flow from operating activities during the period amounted to SEK 36.7 (26.0) million. The increase is explained primarily of an increased EBITDA adjusted for share-based bonus program, but also due to withholding payments of SEK 8.4 million to a supplier because of inaccurate VAT charging from the supplier. The amount will be paid during the period and then have a negative impact on the cash flow. Working capital in inventory increased primarily due to an increased number of XPS™-machines in the inventory compared with last year. Cash flow from investment activities amounted to SEK -57.5 (-41.3) million, whereof SEK -54.4 (-35.7) million was invested in intangible assets and SEK 3.1 (5.6) million was invested in tangible assets. Cash and cash equivalents at the end of the period amounted to SEK 197.6 (201.2) 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 89 (92) percent at the end of the period.

## **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. This means that the study can be started in Sweden and that applications to the other EU countries that will participate in the study can be submitted to the national ethics committees. 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 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 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.

## **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 second quarter of 2019 increased by 198,000 shares and votes. As of September 30, 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.

## **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.

## **OUTLOOK FOR 2019 AND 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 2019 and 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 and the US 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 period, the number of employees was 51, of whom 23 were women and 28 were men. Of these, 34 people were employed in Sweden and 17 outside Sweden. In addition, the company uses around 10 consultants.

### Information on transactions with related parties

During the period, one transaction with the Board member Folke Nilsson has been conducted amounting to SEK 42 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  
Joachim Spetz, appointed by Swedbank Robur  
Martin Lewin, appointed by Eccenovo AB  
Gösta Johannesson, Chairman of the Board

The appointments have been made in accordance with the instructions regarding principles for the appointment of the company Nomination Committee which were determined at the Annual General Meeting of XVIVO Perfusion AB (publ) on April 27, 2018. The members of the Nomination Committee together represent 28 percent of the votes attached to all voting shares in the company.

### Annual General Meeting

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.

### Events after the end of the reporting period

XVIVO has decided to start an Australian wholly owned subsidiary in the fourth quarter. Initially, the strategy is to strengthen the local presence in Australia and New Zealand with its own staff in order to meet the great interest in the region for XVIVO's heart preservation project and products and services for EVLP.

The company's warrant program (series 2019/2021) has been closed. The 2019 Annual General Meeting resolved to issue a maximum of 351,000 warrants with the consequent right to subscribe for a maximum of 351,000 new shares to employees of the XVIVO Perfusion Group. Of these, all 351,000 warrants were subscribed. The warrants give the holder the right to subscribe for a new share in May 2021 at a price of SEK 278.91.

The above events have no impact on the assessment of the financial information in this report. No other significant events have occurred after the reporting period.

Gothenburg  
October 24, 2019

The Board

## Review report

To the Board of Directors of XVIVO Perfusion AB (publ.)  
Corp. id. 556561-0424

### Introduction

We have reviewed the summary interim financial information (interim report) of XVIVO Perfusion AB (publ.) as of 30 September 2019 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

### Scope of review

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

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with

IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Göteborg 24 October 2019

KPMG AB

Jan Malm  
Authorized Public Accountant

### Financial reports

XVIVO Perfusion's interim reports are published on the company's website, [www.xvivoperfusion.com](http://www.xvivoperfusion.com). Following reports are planned to be submitted:

Report on Operations 2019: Thursday, January 30, 2020.  
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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*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 October 24, 2019 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

SEK THOUSANDS	January - September		July - September		Whole year
	2019	2018	2019	2018	2018
Net sales	158 421	129 479	54 334	40 914	187 868
Cost of goods sold	-41 314	-35 300	-15 791	-9 876	-51 915
<b>Gross income</b>	<b>117 107</b>	<b>94 179</b>	<b>38 543</b>	<b>31 038</b>	<b>135 953</b>
Selling expenses	-42 414	-33 782	-14 376	-11 846	-47 948
Administrative expenses	-17 587	-14 711	-6 029	-5 513	-22 519
Research and development costs	-44 687	-35 371	-16 827	-11 734	-47 931
Other operating revenues and expenses*	-10 075	-2 429	966	-1 207	-3 555
<b>Operating income</b>	<b>2 344</b>	<b>7 886</b>	<b>2 277</b>	<b>738</b>	<b>14 000</b>
Financial income and expenses	5 188	2 290	3 210	-803	3 498
<b>Income after financial items</b>	<b>7 532</b>	<b>10 176</b>	<b>5 487</b>	<b>-65</b>	<b>17 498</b>
Taxes	-691	-2 376	-558	164	-4 813
<b>Net income</b>	<b>6 841</b>	<b>7 800</b>	<b>4 929</b>	<b>99</b>	<b>12 685</b>
<b>Attributable to</b>					
Parent Company's shareholders	<b>6 841</b>	<b>7 800</b>	<b>4 929</b>	<b>99</b>	<b>12 685</b>
Earnings per share, SEK	0,26	0,30	0,19	0,00	0,48
Earnings per share, SEK**	0,26	0,30	0,18	0,00	0,48
Average number of outstanding shares	26 491 229	26 269 015	26 600 496	26 402 496	26 302 385
Average number of outstanding shares**	26 826 496	26 397 015	26 879 496	26 786 496	26 302 385
Number of shares at closing day	26 600 496	26 402 496	26 600 496	26 402 496	26 402 496
Number of shares at closing day**	26 879 496	26 879 496	26 879 496	26 879 496	26 402 496
<b>EBITDA</b>	<b>20 321</b>	<b>20 438</b>	<b>9 025</b>	<b>5 207</b>	<b>30 923</b>
Amortization	-10 432	-8 136	-4 099	-2 736	-10 861
Depreciation	-7 545	-4 416	-2 649	-1 733	-6 062
<b>Operating income</b>	<b>2 344</b>	<b>7 886</b>	<b>2 277</b>	<b>738</b>	<b>14 000</b>

\* 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-September 2019, the cost amounted to SEK -7 283 thousand (-3 612). During the third quarter the cost was positive of SEK 2 253 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

SEK THOUSANDS	January - September		July - September		Whole year
	2019	2018	2019	2018	2018
<b>Net income</b>	<b>6 841</b>	<b>7 800</b>	<b>4 929</b>	<b>99</b>	<b>12 685</b>
<b>Other comprehensive income</b>					
<i>Items that may be reclassified to the income statement</i>					
Exchange rate differences	7 412	3 749	4 531	-801	4 875
Tax attributable to items that have been transferred, or can be transferred to net income	-857	-309	-487	81	-473
<b>Total other comprehensive income, net after tax</b>	<b>6 555</b>	<b>3 440</b>	<b>4 044</b>	<b>-720</b>	<b>4 402</b>
<b>Total comprehensive income</b>	<b>13 396</b>	<b>11 240</b>	<b>8 973</b>	<b>-621</b>	<b>17 087</b>
<b>Attributable to</b>					
Parent Company's shareholders	13 396	11 240	8 973	-621	17 087

# CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK THOUSANDS	Sept 30, 2019	Sept 30, 2018	Dec 31, 2018
<b>ASSETS</b>			
Goodwill	65 998	65 561	65 614
Capitalized development expenditure	252 819	200 946	210 460
Other intangible fixed assets	5 237	3 470	3 624
Fixed assets	23 014	17 711	15 615
Financial assets	12 594	17 968	13 619
<b>Total non-current assets</b>	<b>359 662</b>	<b>305 656</b>	<b>308 932</b>
Inventories	47 110	36 145	36 387
Current receivables	52 807	35 697	54 229
Liquid funds	197 643	201 248	187 064
<b>Total current assets</b>	<b>297 560</b>	<b>273 090</b>	<b>277 680</b>
<b>Total assets</b>	<b>657 222</b>	<b>578 746</b>	<b>586 612</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
Shareholders' equity, attributable to the Parent Company's shareholders	582 623	534 630	540 477
Long-term interest-bearing liabilities	3 010	-	-
Long-term non-interest-bearing liabilities	3 551	3 295	3 562
Short-term interest-bearing liabilities	3 396	-	-
Short-term non-interest-bearing liabilities	64 642	40 821	42 573
<b>Total shareholders' equity and liabilities</b>	<b>657 222</b>	<b>578 746</b>	<b>586 612</b>

## CONSOLIDATED KEY RATIOS

	January - September		July - September		Whole year
	2019	2018	2019	2018	2018
Gross margin non-Durable goods, %	77	77	77	77	77
Gross margin, %	74	73	71	76	72
EBITDA, %	13	16	17	13	16
Operating margin, %	1	6	4	2	7
Net margin, %	4	6	9	0	7
Equity/assets ratio, %	89	92	89	92	92
Income per share, SEK	0,26	0,30	0,19	0,00	0,48
Shareholders' equity per share, SEK	21,90	20,25	21,90	20,25	20,47
Share price on closing day, SEK	173,00	146,60	173,00	146,60	132,00

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

## CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEKTHOUSANDS	January - September 2019		July - September 2018		Whole year 2018
Income after financial items	7 531	10 176	5 486	-65	17 497
Adjustment for items not affecting cash flow	16 140	13 051	6 355	3 576	15 263
Paid taxes	-2 763	69	-1 202	-582	628
Change in inventories	-10 370	-2 413	-1 515	-6 954	-2 311
Change in trade receivables	5 750	635	3 331	4 342	-17 236
Change in trade payables	20 435	4 482	3 122	3 416	9 786
<b>Cash flow from operating activities</b>	<b>36 723</b>	<b>26 000</b>	<b>15 577</b>	<b>3 733</b>	<b>23 627</b>
Cash flow from investing activities	-57 503	-41 288	-18 024	-11 263	-53 198
Cash flow from financing activities	26 237	19 204	-758	-79	19 204
<b>Cash flow for the period</b>	<b>5 457</b>	<b>3 916</b>	<b>-3 205</b>	<b>-7 609</b>	<b>-10 367</b>
Liquid funds at beginning of period	187 064	195 322	198 215	209 038	195 322
Exchange rate difference in liquid funds	5 122	2 010	2 633	-181	2 109
<b>Liquid funds at end of period</b>	<b>197 643</b>	<b>201 248</b>	<b>197 643</b>	<b>201 248</b>	<b>187 064</b>

## CONSOLIDATED CHANGES IN SHAREHOLDERS EQUITY

SEKTHOUSANDS	Attributable to Parent Company's shareholders				Sum shareholders' equity
	Share capital	Other paid in capital	Reserves	Retained ear- nings incl. profit for the year	
<b>Shareholders' equity as of 1 January, 2018</b>	<b>670</b>	<b>467 661</b>	<b>8 618</b>	<b>27 237</b>	<b>504 186</b>
Total comprehensive income Jan - Sept, 2018			3 440	7 800	11 240
Share warrant program		182			182
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	5	19 017			19 022
<b>Shareholders' equity as of 30 September, 2018</b>	<b>675</b>	<b>486 860</b>	<b>12 058</b>	<b>35 037</b>	<b>534 630</b>
Total comprehensive income October - December, 2018			962	4 885	5 847
<b>Shareholders' equity as of 31 december, 2018</b>	<b>675</b>	<b>486 860</b>	<b>13 020</b>	<b>39 922</b>	<b>540 477</b>
Total comprehensive income January - Sept, 2019			6 555	6 841	13 396
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	5	27 321			27 326
Share warrant program		1 424			1 424
<b>Shareholders' equity as of 30 Sept, 2019</b>	<b>680</b>	<b>515 605</b>	<b>19 575</b>	<b>46 763</b>	<b>582 623</b>

## CONDENSED CONSOLIDATED STATEMENT OF NET INCOME PER QUARTER

SEKTHOUSANDS	Jul - Sep 2019	Apr - Jun 2019	Jan - Mar 2019	Oct - Dec 2018	Jul - Sep 2018	Apr - Jun 2018	Jan - Mar 2018	Oct - Dec 2017
Net sales	54 334	56 437	47 650	58 389	40 914	46 090	42 475	41 568
Cost of goods sold	-15 791	-14 789	-10 734	-16 615	-9 876	-13 061	-12 363	-9 731
<b>Gross income</b>	<b>38 543</b>	<b>41 648</b>	<b>36 916</b>	<b>41 774</b>	<b>31 038</b>	<b>33 029</b>	<b>30 112</b>	<b>31 837</b>
Selling expenses	-14 376	-15 957	-12 081	-14 166	-11 846	-11 549	-10 387	-10 819
Administrative expenses	-6 029	-6 148	-5 410	-7 808	-5 513	-4 684	-4 514	-5 391
Research and development costs	-16 827	-12 898	-14 962	-12 560	-11 734	-12 100	-11 537	-10 121
Other operating revenues and expenses*	966	-4 716	-6 325	-1 126	-1 207	-697	-525	-767
<b>Operating income</b>	<b>2 277</b>	<b>1 929</b>	<b>-1 862</b>	<b>6 114</b>	<b>738</b>	<b>3 999</b>	<b>3 149</b>	<b>4 739</b>
Financial income and expenses	3 210	527	1 451	1 208	-803	1 315	1 778	763
<b>Income after financial items</b>	<b>5 487</b>	<b>2 456</b>	<b>-411</b>	<b>7 322</b>	<b>-65</b>	<b>5 314</b>	<b>4 927</b>	<b>5 502</b>
Taxes	-558	-229	96	-2 437	164	-1 420	-1 120	64
<b>Net income</b>	<b>4 929</b>	<b>2 227</b>	<b>-315</b>	<b>4 885</b>	<b>99</b>	<b>3 894</b>	<b>3 807</b>	<b>5 566</b>
<b>Attributable to</b>								
Parent Company's shareholders	4 929	2 227	-315	4 885	99	3 894	3 807	5 566
Earnings per share, SEK	0,19	0,08	-0,01	0,19	0,00	0,15	0,15	0,21
Earnings per share, SEK**	0,18	0,08	-0,01	0,19	0,00	0,15	0,15	0,21
Average number of outstanding shares	26 600 496	26 532 296	26 402 496	26 402 496	26 402 496	26 378 940	26 190 496	26 190 496
Average number of outstanding shares**	26 879 496	26 879 496	26 720 496	26 402 496	26 786 496	26 378 940	26 190 496	26 402 496
Number of shares at closing day	26 600 496	26 600 496	26 402 496	26 402 496	26 402 496	26 402 496	26 190 496	26 190 496
Number of shares at closing day**	26 879 496	26 879 496	26 879 496	26 402 496	26 879 496	26 402 496	26 190 496	26 402 496
<b>EBITDA</b>	<b>9 025</b>	<b>8 055</b>	<b>3 241</b>	<b>10 485</b>	<b>5 207</b>	<b>8 075</b>	<b>7 156</b>	<b>8 585</b>
Amortization	-4 099	-3 618	-2 715	-2 725	-2 736	-2 699	-2 701	-2 639
Depreciation	-2 649	-2 508	-2 388	-1 646	-1 733	-1 377	-1 306	-1 207
<b>Operating income</b>	<b>2 277</b>	<b>1 929</b>	<b>-1 862</b>	<b>6 114</b>	<b>738</b>	<b>3 999</b>	<b>3 149</b>	<b>4 739</b>

\* 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 third quarter the cost was positive of SEK 2 253 thousand (-812) due to resolution of a provision. 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	Jul - Sep 2019	Apr - Jun 2019	Jan - Mar 2019	Oct - Dec 2018	Jul - Sep 2018	Apr - Jun 2018	Jan - Mar 2018	Oct - Dec 2017
<b>Net income</b>	<b>4 929</b>	<b>2 227</b>	<b>-315</b>	<b>4 885</b>	<b>99</b>	<b>3 894</b>	<b>3 807</b>	<b>5 566</b>
<b>Other comprehensive income</b> <i>Items that may be reclassified to the income statement</i>								
Exchange rate differences	4 531	30	2 851	1 126	-801	4 413	137	509
Tax attributable to items that have been transferred, or can be transferred to net income	-487	-20	-350	-164	81	-466	76	-27
<b>Total other comprehensive income, net after tax</b>	<b>4 044</b>	<b>10</b>	<b>2 501</b>	<b>962</b>	<b>-720</b>	<b>3 947</b>	<b>213</b>	<b>482</b>
<b>Total comprehensive income</b>	<b>8 973</b>	<b>2 237</b>	<b>2 186</b>	<b>5 847</b>	<b>-621</b>	<b>7 841</b>	<b>4 020</b>	<b>6 048</b>
<b>Attributable to</b>								
Parent Company's shareholders	8 973	2 237	2 186	5 847	-621	7 841	4 020	6 048

## CONDENSED INCOME STATEMENT FOR THE PARENT COMPANY

SEKTHOUSANDS	January - September		July - September		Whole year
	2019	2018	2019	2018	2018
Net sales	121 871	111 335	39 617	41 432	152 332
Cost of goods sold	-33 163	-28 794	-13 761	-10 203	-39 735
<b>Gross income</b>	<b>88 708</b>	<b>82 541</b>	<b>25 856</b>	<b>31 229</b>	<b>112 597</b>
Selling expenses	-26 587	-19 545	-8 114	-6 461	-27 940
Administrative expenses	-11 889	-7 578	-3 953	-3 407	-12 578
Research and development costs	-49 646	-33 812	-17 277	-12 657	-46 074
Other operating revenues and expenses	-3 161	-1 939	-2 343	-832	-2 643
<b>Operating income</b>	<b>-2 575</b>	<b>19 667</b>	<b>-5 831</b>	<b>7 872</b>	<b>23 362</b>
Financial income and expenses	9 840	4 284	5 639	-900	6 460
<b>Income after financial items</b>	<b>7 265</b>	<b>23 951</b>	<b>-192</b>	<b>6 972</b>	<b>29 822</b>
Year end dispositions	-	-	-	-	-19 537
Taxes	-382	-5 441	204	-1 575	-2 487
<b>Net income</b>	<b>6 883</b>	<b>18 510</b>	<b>12</b>	<b>5 397</b>	<b>7 798</b>

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 7 890 (6 906) thousand, of which SEK 4 413 thousand (3 447) for the quarter.

## CONDENSED BALANCE SHEET FOR THE PARENT COMPANY

SEKTHOUSANDS	Sept 30, 2019	Sept 30, 2018	Dec 31, 2018
<b>ASSETS</b>			
Intangible fixed assets	190 794	139 416	149 153
Fixed assets	6 030	7 962	7 367
Financial assets	193 966	200 627	200 222
<b>Total non-current assets</b>	<b>390 790</b>	<b>348 005</b>	<b>356 742</b>
Inventories	16 593	12 085	14 360
Current receivables	35 762	20 493	27 687
Cash and bank	183 260	190 294	178 248
<b>Total current assets</b>	<b>235 615</b>	<b>222 872</b>	<b>220 295</b>
<b>Total assets</b>	<b>626 405</b>	<b>570 877</b>	<b>577 037</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
Shareholders' equity	554 860	529 959	519 247
Untaxed reserves	10 150	8 913	10 150
Provisions	1 318	1 334	1 329
Short-term non-interest-bearing liabilities	60 077	30 671	46 311
<b>Total shareholders' equity and liabilities</b>	<b>626 405</b>	<b>570 877</b>	<b>577 037</b>

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, September 30, 2019, the Group reports the following book values of leased assets: Tangible assets SEK 6 406 (-) thousand. The effect of IFRS 16 in the consolidated income statement for the period January-September, 2019, is that depreciation of SEK 2.493 thousand and interest expense of SEK 128 thousand replaced operating leasing cost of SEK 2.621 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 September 30, 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-June 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 - September		Durable goods		Total consolidated	
	Net sales of non-Durable goods		2019	2018	2019	2018
	2019	2018				
Net sales	147 456	120 360	10 965	9 119	158 421	129 479
Cost of goods sold	-33 668	-27 885	-7 646	-7 415	-41 314	-35 300
<b>Gross income</b>	<b>113 788</b>	<b>92 475</b>	<b>3 319</b>	<b>1 704</b>	<b>117 107</b>	<b>94 179</b>

SEK Thousands	July - September		Durable goods		Total consolidated	
	Net sales of non-Durable goods		2019	2018	2019	2018
	2019	2018				
Net sales	50 137	40 251	4 197	663	54 334	40 914
Cost of goods sold	-11 677	-9 413	-4 114	-463	-15 791	-9 876
<b>Gross income</b>	<b>38 460</b>	<b>30 838</b>	<b>83</b>	<b>200</b>	<b>38 543</b>	<b>31 038</b>

## Note 4. Financial instruments

The Group's financial assets and liabilities valued at acquisition value amount to SEK 250 (237) million and SEK 65 (40) 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 - September		July - September		Whole year
	2019	2018	2019	2018	2018
<b>Operating income</b>	<b>2 344</b>	<b>7 886</b>	<b>2 277</b>	<b>738</b>	<b>14 000</b>
Amortization	10 432	8 136	4 099	2 736	10 861
Depreciation	7 545	4 416	2 649	1 733	6 062
<b>EBITDA</b>	<b>20 321</b>	<b>20 438</b>	<b>9 025</b>	<b>5 207</b>	<b>30 923</b>

### Gross margin

SEK THOUSANDS	January - September		July - September		Whole year
	2019	2018	2019	2018	2018
Operating income					
Net sales	158 421	129 479	54 334	40 914	187 868
Operating expenses					
Cost of goods sold	-41 314	-35 300	-15 791	-9 876	-51 915
<b>Gross income</b>	<b>117 107</b>	<b>94 179</b>	<b>38 543</b>	<b>31 038</b>	<b>135 953</b>
<b>Gross margin %</b>	<b>74</b>	<b>73</b>	<b>71</b>	<b>76</b>	<b>72</b>

## Gross margin non-Durable goods

SEK THOUSANDS	January - September 2019		July - September 2019		Whole year 2018
Operating income					
Net sales of non-Durable goods	147 456	120 360	50 137	40 251	140 994
Operating expenses					
Cost of non-Durable goods sold	-33 668	-27 885	-11 677	-9 413	-30 362
<b>Gross income, non-Durable goods</b>	<b>113 788</b>	<b>92 475</b>	<b>38 460</b>	<b>30 838</b>	<b>110 632</b>
<b>Gross margin, non-Durable goods %</b>	<b>77</b>	<b>77</b>	<b>77</b>	<b>77</b>	<b>78</b>

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	Sept 30, 2019	Sept 30, 2018	Dec 31, 2018
Shareholders' equity	582 623	534 630	540 477
Total assets	657 222	578 746	586 612
<b>Equity/assets ratio %</b>	<b>89</b>	<b>92</b>	<b>92</b>

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
<b>Gross margin non-Durable goods, %</b>	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.
<b>Gross margin, %</b>	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.
<b>EBITDA margin, %</b>	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.
<b>Operating margin, %</b>	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.
<b>Net margin, %</b>	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.
<b>Equity/assets ratio, %</b>	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.
<b>Shareholders' equity per share, SEK</b>	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.
<b>Earnings per share, SEK</b>	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.
<b>Earnings per share after dilution, SEK</b>	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.

### 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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