



# INTERIM REPORT JANUARY–SEPTEMBER 2017 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®, has a market share of more than 90 percent in the traditional preservation of lungs for transplantation. The company's products for warm perfusion, XPS™ and STEEN Solution™, have regulatory approval in all major markets, and are the only products to date to have received regulatory approval from the FDA for warm perfusion of lungs. XVIVO Perfusion employs approximately 30 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.*

**XVIVO**  
PERFUSION

# CONTINUED GROWTH AND PROGRESS IN THREE DEVELOPMENT PROJECTS

## THIRD QUARTER 2017 (JUL - SEP)

- Net sales of non-durable goods in the quarter amounted to SEK 31.6 (29.1) million, corresponding to an increase of 8 percent in SEK. Sales of non-durable goods increased by 11 percent in local currency. Net sales in the quarter amounted to SEK 32.3 (31.7) million, corresponding to an increase of 2 percent. The increase corresponds to 4 percent in local currency.
  - Operating income before depreciation and amortization (EBITDA), excluding items affecting comparability, amounted to SEK 4.4 (5.4) million, corresponding to an EBITDA margin of 14 percent. Items affecting comparability of SEK 0.4 (2.7) million, related to the acquisition and integration of Vivoline, have been charged against the quarter. EBITDA amounted to SEK 4.1 (2.7) million, corresponding to an EBITDA margin of 13 percent.
  - Operating income amounted to SEK 0.4 (-0.7) million, after amortization and depreciation of SEK 3.7 (3.5) million was charged against the quarter.
  - Net income amounted to SEK -0.4 (-0.6) million, resulting in earnings per share of SEK -0.01 (-0.02).
  - Cash flow from operating activities was SEK 7.6 (5.4) million.
- Warm perfusion sales from non-durable goods (STEEN Solution™, products and services related to the use of the XPS™ and LS™\*) accounted for 30 (29) percent of the total sales of non-durable goods.
  - Inclusion of all 220 (110 + 110) patients is now completed in the NOVEL study which is being carried out in the US on STEEN Solution™ and XPS™. This clinical study will form the basis of the company's PMA (Pre-market Approval) application to the FDA. STEEN Solution™ and XPS™ have already been approved for sales in the US under an HDE (Humanitarian Device Exemption) approval.
  - Recruitment is completed for the PrimECC® study at Sahlgrenska University Hospital. The study intends to expand the clinical documentation for PrimECC® and included a total of 80 (40 + 40) patients.
  - The first clinical heart transplant using the heart preservation technology developed by XVIVO's partner Professor Stig Steen was performed during the quarter. His research has resulted in a heart preservation technology that makes it possible to transport and store the donor heart in a more optimized way than before. Earlier animal experiments have shown that the method has the potential to extend the time that the heart is stored outside the body (Ex Vivo).

## THE PERIOD 2017 (JAN - SEP)

- Net sales of non-Durable goods in the period amounted to SEK 101.6 (88.0) million, corresponding to an increase of 15 percent in SEK. Sales of non-Durable goods increased by 13 percent in local currency. Net sales in the period amounted to SEK 106.8 (99.8) million, corresponding to an increase of 7 percent. The increase corresponds to 4 percent in local currency.
  - Operating income before depreciation and amortization (EBITDA), excluding items affecting comparability, amounted to SEK 15.7 (19.7) million, corresponding to an EBITDA, excluding items affecting comparability, margin of 15 percent. Items affecting comparability of SEK 2.3 (7.3) million, related to the acquisition and integration of Vivoline, have been charged against the period. EBITDA amounted to SEK 13.4 (12.4) million, corresponding to an EBITDA margin of 13 percent.
  - Operating income amounted to SEK 2.4 (2.7) million, after amortization and depreciation of SEK 11.1 (9.7) million was charged against the period.
- Net income amounted to SEK 0.7 (2.1) million, resulting in earnings per share of SEK 0.03 (0.09).
  - Cash flow from operating activities was SEK 14.3 (18.7) million.
  - Warm perfusion sales from non-durable goods (STEEN Solution™, products and services related to the use of the XPS™ and LS™\*) accounted for 32 (31) percent of the total sales of non-Durable goods.
  - A Private Placement was fully subscribed by the Third AP Fund, Norron, Swedbank Robur and the Fourth AP Fund and it raised approximately SEK 181 million before issue costs.
  - Two XPS™ were sold during the period; one XPS™ to Australia and one XPS™ to the Netherlands. Both countries are new countries with an XPS™. At the end of the period 45 clinics had access to the XPS™ or LS™.

## MILESTONES PASSED UNTIL PUBLICATION OF THE INTERIM REPORT

All 220 patients included in the NOVEL study in the US which will form the basis of the company's PMA application there.

The first clinical heart transplant using the heart preservation technology developed by XVIVO's partner Professor Stig Steen was performed.

PrimECC study on 80 patients at Sahlgrenska University Hospital completed. Analysis of the results is ongoing.

### CEO'S COMMENTS



The third quarter was eventful and important steps in the right direction have been taken in several of XVIVO Perfusion's prioritized product development projects, at the same time as the company continues to maintain both a good growth rate and a positive EBITDA.

During the quarter recruitment was completed for the NOVEL study in the US on 220 (110+110) lung transplant patients using STEEN Solution™ and XPS™. This study is extremely important for the company. It evaluates initially refused lungs and the lungs that are approved in the evaluation are then used for transplantation. An average of just over half of the lungs evaluated are given to patients. The NOVEL study has a one-year follow-up and the results from the study will form the basis of the company's PMA application to the FDA. In parallel with this study, the compulsory PAS (Post-Marketing Study) is being performed. This includes the same 220 patients plus a further 16 patients in each group. When recruitment for PAS is also completed (only 8 patients remain at present) the restriction that the study imposes on the clinics regarding recruitment of donated lungs and patients for EVLP will no longer apply. In collaboration with the clinics, the company will then be able to focus more on tailoring the technology for customers, building up the market and customer service.

The inclusion in the clinical PrimECC study on 80 (40 + 40) patients was completed during the quarter. The randomized, double-blinded study examined whether it was possible to improve patients' condition after having undergone surgery using a heart-lung machine when PrimECC was used in the machine. The company assesses that analysis of the results will be completed and available during the fourth quarter this year or early 2018.

Another important milestone that passed during the quarter, was the first clinical heart transplant using the heart

preservation technology, developed by Professor Stig Steen's was successfully performed. This revolutionary technology has demonstrated in preclinical trials that donated hearts could be preserved while retaining full function outside the body and furthermore for a considerably longer period of time than what is possible using today's technology. This would allow, if confirmed in studies on humans, that considerably more donated hearts with better function could be used for transplantation and thus more patients' lives could be saved.

XVIVO Perfusion's market launch of lung transplant products is also proceeding at a rapid pace. The trend of increased use of input products in the lung transplantation field continues – growth for sales excluding capital goods during the third quarter was increased by 11 percent in local currency even though the comparative figure are from an unusually strong third quarter in 2016. The company's gross and EBITDA margin during the year continue to display underlying strength in the established business activities. Despite the fact that large investments have been made in R&D as well as in the building up of the market organization and support functions such as quality assurance and regulatory competence.

The focus for the lung transplant area is to expand the installation base of the company's EVLP machines and in parallel to increase the resources for training and service for the clinics. XVIVO will continue to develop the EVLP technology in order to support the transplantation clinics in their efforts to treat more patients on the waiting lists. The focus of XVIVO's research is to continue to lead the development of innovative solutions in the field of thorax surgery and to develop the use of perfusion in more organs for transplantation. The company also conducts research in the use of the same technology for treatment of isolated organs and tissue still in the body, for example the administration of cytotoxins to isolated lungs affected by metastases.

Magnus Nilsson  
CEO

### CONFERENCE CALL

CEO Magnus Nilsson will present the report in a conference call at 2 p.m. CET on Friday, October 27, 2017. Telephone UK: +44 (0) 203 139 4830 or USA: +1 718 873 9077, enter code 20105534#.

## THIRD QUARTER 2017 (JULY - SEPTEMBER)

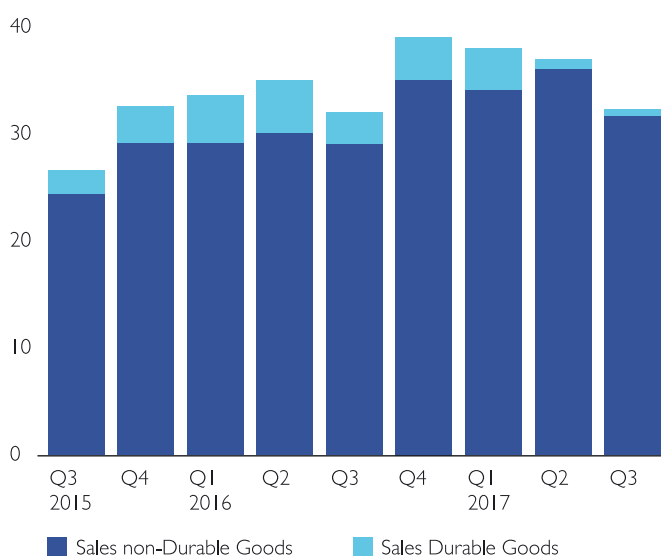
### Net Sales

XVIVO Perfusion's net sales of non-durable goods\* in the quarter amounted to SEK 31.6 (29.1) million, corresponding to an

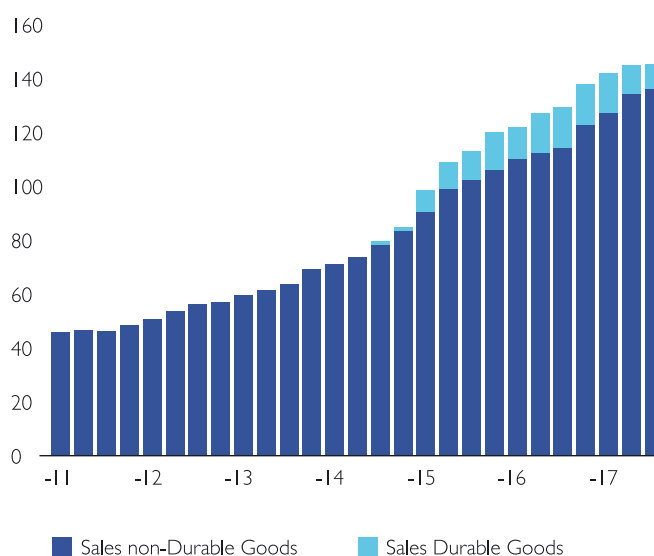
increase of 8 percent in SEK and 11 percent in local currency. Total net sales in the quarter amounted to SEK 32.3 (31.7) million, corresponding to an increase of 2 percent in SEK and 4 percent in local currency.

Warm perfusion sales from non-durable goods (STEEN Solution™, products and services related to the use of the

NET SALES PER QUARTER (SEK MILLIONS)\*



NET SALES ROLLING 12 MONTHS (SEK MILLIONS)\*



## COMPILATION OF NET SALES AND EBITDA

SEK THOUSANDS	January - September		July - September		Whole year
	2017	2016	2017	2016	2016
Net Sales non-Durable Goods	101 552	87 975	31 573	29 140	122 527
Net Sales Durable Goods	5 222	11 784	690	2 590	15 650
<b>Net Sales Total</b>	<b>106 774</b>	<b>99 759</b>	<b>32 263</b>	<b>31 730</b>	<b>138 177</b>
Cost of Goods non-Durable Goods	-21 496	-17 862	-7 004	-5 738	-24 798
Cost of Goods Durable goods	-3 719	-8 550	0	-1 756	-11 144
Cost of Goods Total	-25 215	-26 412	-7 004	-7 494	-35 942
Gross income non-Durable Goods	80 056	70 113	24 569	23 402	97 729
Gross margin non-Durable Goods, %	79%	80%	78%	80%	80%
Gross income Durable Goods	1 503	3 234	690	834	4 506
Gross income Total	81 559	73 347	25 259	24 236	102 235
Gross margin Total, %	76%	74%	78%	76%	74%
Selling expenses	-32 883	-25 396	-10 384	-9 770	-35 708
Administrative expenses	-14 654	-17 738	-4 662	-5 418	-24 489
Research and development costs	-29 348	-25 642	-8 883	-9 033	-36 670
Other operating revenues and expenses	-2 307	-1 863	-941	-747	-2 634
<b>Operating Income</b>	<b>2 367</b>	<b>2 708</b>	<b>389</b>	<b>-732</b>	<b>2 734</b>
amortization and depreciation cost of goods sold	-367	-182	-98	-182	-297
depreciation administrative expenses	-607	-332	-227	-114	-484
amortization of research and development expenses	-7 913	-7 728	-2 638	-2 617	-10 346
depreciation other operative expenses	-2 184	-1 416	-725	-556	-2 091
<b>EBITDA</b>	<b>13 438</b>	<b>12 366</b>	<b>4 077</b>	<b>2 737</b>	<b>15 952</b>
EBITDA, %	13%	12%	13%	9%	12%
Items affecting comparability	-2 280	-7 312	-365	-2 692	-10 399
EBITDA excluding items affecting comparability	15 718	19 678	4 442	5 429	26 351
EBITDA excluding items affecting comparability, %	15%	20%	14%	17%	19%

XPST<sup>™</sup> and LS<sup>™</sup>) accounted for 30 (29) percent of the total sales of non-Durable goods. Total sales from warm perfusion (STEEN Solution<sup>™</sup>, XPST<sup>™</sup>, LS<sup>™</sup>, and products and services related to the use of the XPST<sup>™</sup> and LS<sup>™</sup>) accounted for 32 (35) percent of the total sales.

## Income

Operating income before depreciation and amortization (EBITDA), excluding items affecting comparability, amounted to SEK 4.4 (5.4) million, corresponding to an EBITDA, excluding items affecting comparability, margin of 14 percent. The main reason for the decrease is that increased investments in Sales and Marketing were made during the quarter, which is deemed to be positive for sales in the long term. Items affecting comparability of SEK 0.4 (2.7) million have been charged against the quarter, whereof SEK 0.1 million are transaction costs related to the Vivoline acquisition, and SEK 0.3 million are integration costs related to the integration of Vivoline. EBITDA amounted to SEK 4.1 (2.7) million, corresponding to an EBITDA margin of 13 percent.

Operating income amounted to SEK 0.4 (-0.7) million, after amortization and depreciation of SEK 3.7 (3.5) million was charged against the quarter.

The gross margin for non-Durable goods during the quarter was 78 (80) percent. The total gross margin during the quarter was 78 (76) percent. The increase is attributable to segment mix.

Selling expenses in relation to sales increased during the quarter to 32 (31) percent, mainly due to three more employees and increased resources on service and marketing. R&D expenses amounted to 28 (28) percent of sales. Administrative expenses decreased to 14 (17) percent of sales, mainly due to less items affecting comparability. The administration department has one more head count and higher costs due to the listing on Nasdaq Stockholm main list. Net other operating revenues and expenses during the quarter were SEK -0.9 (-0.7) million.

During the quarter, SEK 7.4 (3.0) million of the development costs were capitalized as an intangible asset. SEK 4.2 (1.5) million was attributable to the continued NOVEL study with STEEN Solution<sup>™</sup> with the aim of PMA approval. SEK 2.9 (0.9) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, and SEK 0.2 (0.6) million was attributable to product development of the product portfolio. Depreciation and amortization for the period amounted to SEK 3.7 (3.5) million, of which SEK 2.4 (2.4) million was amortization of the FDA HDE approval.

## Cash flow

Cash flow from operating activities amounted to SEK 7.6 (5.4). Investments amounted to SEK 9.3 (7.6) million, of which SEK 7.6 (3.5) million was invested in intangible assets and SEK 1.3

(3.9) million was invested in tangible assets. Acquisitions of Vivoline amounted to SEK 0.5 million during the quarter. The cash flow from financing activities was SEK -0.1 (0.0) million. Cash and cash equivalents at the end of the quarter amounted to SEK 200.8 (40.1) million.

## First clinical heart transplant performed using the method developed by XVIVO's partner Professor Stig Steen

Through its collaboration agreement with Igelösa, XVIVO Perfusion has the commercial rights to Professor Stig Steen's research on heart transplants. The research has resulted in a method in connection with heart transplants that makes it possible to transport and preserve the heart from a donor in a more optimized way. Previous animal experiments have demonstrated that the method has the potential to extend the time a heart can be preserved outside the body (Ex Vivo). The first clinical heart transplant using the new method has now been successfully performed.

Approximately 6,500 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 before transplantation. In previous animal experiments using the new method, the preservation time for the donated heart has been extended from today's approximately four hours to approximately 12 hours.

If the new method proves to work as well in human beings as in animals, it will be possible to use considerably more hearts for transplantation. In the longer term this will mean that the most suitable recipient can receive the donated organ with distance being less of a limiting factor.

## Recruitment completed for NOVEL study in the US on STEEN Solution<sup>™</sup> and XPST<sup>™</sup>

Inclusion of all 220 (110 + 110) patients is now completed in the NOVEL study which is being carried out in the US on STEEN Solution<sup>™</sup> and XPST<sup>™</sup>. This clinical study will form the basis of the company's PMA (Pre-market Approval) application to the FDA. Approximately 40 percent of all lung transplantations in the world are done in the US and STEEN Solution<sup>™</sup> and XPST<sup>™</sup> have already been approved for sales in the US under an HDE (Humanitarian Device Exemption) approval.

In March 2014 the Advisory Panel convened by the FDA voted unanimously, by 10 votes to 0, that the XPST<sup>™</sup> System with STEEN Solution<sup>™</sup> meets the requirements for HDE (Humanitarian Device Exemption) approval. In August 2014 the company received HDE approval from the FDA for the products XPST<sup>™</sup> and STEEN Solution<sup>™</sup> for sales on the American market. HDE approval entails certain restrictions, amongst other things that no more than 4,000 patients may be treated per

year under HDE approval and that separate ethical approval may be required for treatment. The study that has now been completed will form the basis of the company's PMA application, which means that if it is approved, there will no longer be any such restrictions.

The NOVEL study is continuing with follow-up of the patients for up to one year. XVIVO Perfusion has an ongoing dialogue with the FDA about the design and the time for submission of the PMA application and will post information when this has been done. The PAS (Post Approval Study) required by the FDA, which is a compulsory safety follow-up after all approvals, will include a total of 126+126 patients that will be followed for 3 years.

XPS™ is the only CE-marked and FDA-approved (HDE approval) normothermic lung perfusion integrated system on the market today, that provides the clinician the flexibility to evaluate lungs before transplantation by means of a standardized and simplified procedure. XPS™ is used worldwide with good clinical results. The XPS™ and STEEN Solution™ have already been CE-marked and thus approved for sales on the European market, and are also approved for sales in Canada and Australia.

That the PMA study on XPS™ and STEEN Solution™ in the US has completed recruitment is an important step for XVIVO Perfusion. This will mean that as soon as recruitment for the PAS study is complete, some of the restrictions that were part of the clinical trial will disappear and more patients will have an option to receive an EVLP lung. This will also mean that the company can focus more in the US on tailoring the technology for customers, building up the market and customer service

### **Recruitment completed for PrimECC study**

PrimECC® is a CE-marked and patent-protected product, developed to prime the heart-lung machine before open heart surgery. A previous "proof of concept" study performed using PrimECC® has shown interesting clinical results. Recruitment is now completed for a study including a total of 80 patients that aims to increase the clinical documentation for PrimECC®.

Several hundred thousand heart operations are performed in the world each year using a heart-lung machine and the 'proof of concept' study performed using PrimECC® indicates that the patient has an improved fluid balance after the operation if the heart-lung machine is primed with PrimECC® rather than the simpler solutions that are often used. During the past year the company has carried out a randomized, blind clinical study on 80 patients at Sahlgrenska University Hospital in Gothenburg in order to increase the documentation.

XVIVO Perfusion is waiting for analysis of the results from the study at Sahlgrenska University Hospital and does not plan any extensive launch of the product before the results from the

study have been published. XVIVO Perfusion has applied for a patent for PrimECC® in important markets and has so far been granted a patent in the USA, EU, China and Japan.

## **THE PERIOD 2017 (JANUARY - SEPTEMBER)**

### **Net Sales**

XVIVO Perfusion's net sales of non-durable goods\* in the period amounted to SEK 101.6 (88.0) million, corresponding to an increase of 15 percent in SEK and 13 percent in local currency. Total net sales in the period amounted to SEK 106.8 (99.8) million, corresponding to an increase of 7 percent in SEK and 4 percent in local currency.

Warm perfusion sales from non-durable goods (STEEN Solution™, products and services related to the use of the XPS™ and LS™) accounted for 32 (31) percent of the total sales of non-Durable goods. Total sales from warm perfusion (STEEN Solution™, XPS™, LS™, and products and services related to the use of the XPS™ and LS™) accounted for 36 (39) percent of the total sales.

### **Income**

Operating income before depreciation and amortization (EBITDA), excluding items affecting comparability, amounted to SEK 15.7 (19.7) million, corresponding to an EBITDA margin of 15 percent. The main reason for the decrease is that increased investments in Sales and Marketing were made during the period, which is assessed to be positive in the long term. Items affecting comparability of SEK 2.3 (7.3) million have been charged against the period, whereof SEK 0.5 million are transaction costs related to the Vivoline acquisition, and SEK 1.8 million are integration costs related to the integration of Vivoline. EBITDA amounted to SEK 13.4 (12.4) million, corresponding to an EBITDA margin of 13 percent.

Operating income amounted to SEK 2.4 (2.7) million, after amortization and depreciation of SEK 11.1 (9.7) million was charged against the period.

The gross margin for non-Durable goods during the period was 79 (80) percent. The total gross margin during the period was 76 (74) percent.

Selling expenses in relation to sales increased during the period to 31 (25) percent, mainly due to three additional employees and increased resources on service and marketing. R&D expenses amounted to 27 (26) percent of sales. The increase is mainly attributable to two new employees and items affecting comparability amounting to SEK 1.6 million charged against the period. Administrative expenses decreased to 14 (18) percent of sales, mainly due to less items affecting comparability. The administration department has one more head count and

higher costs due to the listing on Nasdaq Stockholm main list. Net other operating revenues and expenses during the period were SEK -2.3 (-1.9) million.

During the period, SEK 19.4 (5.7) million of the development costs were capitalized as an intangible asset. SEK 9.3 (4.2) million was attributable to the continued NOVEL study with STEEN Solution™ with the aim of PMA approval, SEK 9.2 (0.9) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, and SEK 0.9 (0.6) million was attributable to product development of the product portfolio. Depreciation and amortization for the period amounted to SEK 11.1 (9.7) million, of which SEK 7.4 (7.3) million was amortization of the FDA HDE approval.

### Cash flow

Cash flow from operating activities amounted to SEK 14.3 (18.7) million. Investments amounted to SEK 22.0 (20.4) million, of which SEK 20.1 (6.6) million was invested in intangible assets and SEK 1.5 (6.0) million was invested in tangible assets. Acquisitions of Vivoline amounted to SEK 0.5. The cash flow from financing activities was SEK 184.8 (0.2) million and consisted of two new share issues and one warrant program. Cash and cash equivalents at the end of the period amounted to SEK 200.8 (40.1) million.

### Financing

XVIVO Perfusion's total credit facilities consist of an overdraft facility that at the end of the period amounted to SEK 22 (22) million, of which SEK 0.0 (0.0) million was utilized. The equity/assets ratio was 94 (91) percent at the end of the period.

### SEK 181 million share issue directed to four institutional investors

On March 16, 2017, the board of directors of XVIVO Perfusion AB has resolved, with deviation from the shareholders preferential right, upon a new issue of up to 2,361,408 new shares directed to institutional investors. The private placement was fully subscribed by the Third Swedish National Pension Fund (AP3), the Fourth Swedish National Pension Fund (AP4), Norron and Swedbank Robur. The private placement and subscription were subject to approval by an extraordinary general meeting held on 10 April 2017. The extraordinary general meeting approved the new issue of up to 2,361,408 new shares directed to institutional investors.

The subscription price per new share in the private placement was set to SEK 76.50 and has been established through a book-building process. Through the Private Placement, XVIVO Perfusion raised up to approximately SEK 181 million before issue costs. Compared to the past five trading days' volume-weighted average price (5 day VWAP) for XVIVO Perfusion's share on Nasdaq Stockholm during the period 10 to 16 March 2017, the subscription price constituted a discount of 4.5 per cent. Compared to the closing price on 16 March 2017, the

subscription price constituted a discount of 4.7 per cent.

The rationale for carrying out the private placement is to accelerate the company's clinical product development projects, primarily the heart transplant project, with the aim of market registration globally. The board of directors of XVIVO Perfusion assesses that the proceeds from the Private Placement will be sufficient to finance the heart transplant project until market launch. The capital contribution improves the possibility of more rapidly reaching global market approval for the heart transplant products and hence being able to market these products. Furthermore, XVIVO Perfusion will be able to more rapidly take advantage of the potential that exists in the development of new indications e.g. Liver transplantation, PrimECC and Cancer.

## OUTLOOK FOR 2017

As the number of lungs that can be transplanted using traditional cold perfusion cannot be predicted to increase more than the number of lungs donated, it is expected that growth will come primarily from warm perfusion using the STEEN Solution™ method. The focus is therefore, to establish the STEEN Solution™ method as the standard treatment for lung transplantation. Since the acquisition of Vivoline, the company will intensify research and development in cardiac transplantation. Expenses attributable to cardiac transplantation will be capitalized on an ongoing basis. Remaining transaction costs and integration costs related to the acquisition of Vivoline are estimated to be around SEK 1 million, which will be charged against 2017. Integration costs for the Vivoline Acquisition is estimated to SEK 3 million for the year 2017, whereof SEK 2.3 million has been charged to the period January – September 2017.

Organ availability is also the limiting factor for increasing the number of transplantations of organs other than lungs. The focus of research and development is therefore on developing the use of the STEEN Solution™ method for more indications, and on developing other similar areas of use such as the warm perfusion of organs still in the body.

## 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®, has a market share of more than 90 percent in the traditional preservation of lungs for transplantation. The company's products for warm perfusion, XPS™ and STEEN Solution™, have regulatory approval in all major markets, and are the only products to date to have received regulatory approval from the FDA for warm perfusion of 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**

The company conducts preclinical and clinical research in transplantation of organs other than lungs as well as drug delivery to an isolated organ. Through the acquisition of Vivoline, XVIVO Perfusion has access to HSI (machine) and Heartadex™ (solution) for heart transplantation. These products are designed to help increase the use of donated hearts so that more heart transplants can be performed and more patients can be given a last chance of a longer life with better quality of life. The products HSI and Heartadex™ are in phase pre-clinical studies and clinical proof of concept. Future focus is to take the products into phase clinical research and to reach regulatory approval for the products.

### **Other indications**

The company conducts preclinical and clinical research in transplantation of organs other than lungs as well as 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 warm perfusion of organs with XPS™ and STEEN Solution™ as the standard treatment in the transplantation of lungs and other organs.

### **Strategy**

XVIVO Perfusion's strategy is focused on increasing the number

of available transplants for patients. Through published clinical trials, XVIVO Perfusion shows that the warm perfusion of organs with the STEEN Solution™ method gives more available organs and thus a larger number of patients a life-saving treatment and better quality of life, socio-economic profit and lower morbidity and mortality.

## **OTHER INFORMATION**

### **Organization and personnel**

At the end of quarter the number of employees was 29, of whom 13 were women and 16 were men. Of these, 14 people were employed in Sweden and 15 outside Sweden. In addition, the company uses around ten consultants.

### **Information on transactions with related parties**

During the quarter, a transaction with a related party has been conducted. The board member, Folke Nilsson has invoiced the company SEK 36,000 during the quarter.

### **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. Due to the nature of the business, there is a risk of claims for damages and liability. Including financial risks are the currency risk for the business.

The most important strategic and operative risks affecting the company are described in the 2016 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 2018 Annual General Meeting**

The following members have been appointed to XVIVO Perfusion's Nomination Committee for the 2018 Annual General Meeting:



Henrik Blomquist, representing Bure Equity AB  
Martin Lewin, representing Eccenovio AB  
Joachim Spetz, representing Swedbank Robur

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 May 3, 2016. The members of the Nomination Committee together represent 30 percent of the votes attached to all voting shares in the company.

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on April 27, 2018 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

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

Gothenburg  
October 27, 2017

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 2017 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 27 October 2017

KPMG AB

Jan Malm  
Authorized Public Accountant

### This report has been reviewed by the company's auditors.

#### 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 2017: Friday, February 9, 2018  
Interim report January-March 2018: Thursday, April 26, 2018  
Interim Report January-June 2018: Friday, July 13, 2018  
Interim Report January-September 2018: Friday, October 26, 2018  
Report on Operations 2018: Thursday, February 8, 2019

#### For further information, please contact

Magnus Nilsson, CEO, +46 31 788 21 50,  
[magnus.nilsson@xvivoperfusion.com](mailto:magnus.nilsson@xvivoperfusion.com)  
Christoffer Rosenblad, CFO, +46 735 192159,  
[christoffer.rosenblad@xvivoperfusion.com](mailto:christoffer.rosenblad@xvivoperfusion.com)

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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 27, 2017 at 8.00 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
	2017	2016	2017	2016	2016
Net sales	106 774	99 759	32 263	31 730	138 177
Cost of goods sold	-25 215	-26 412	-7 004	-7 494	-35 942
<b>Gross income</b>	<b>81 559</b>	<b>73 347</b>	<b>25 259</b>	<b>24 236</b>	<b>102 235</b>
Selling expenses	-32 883	-25 396	-10 384	-9 770	-35 708
Administrative expenses	-14 654	-17 738	-4 662	-5 418	-24 489
Research and development costs	-29 348	-25 642	-8 883	-9 033	-36 670
Other operating revenues and expenses	-2 307	-1 863	-941	-747	-2 634
<b>Operating income</b>	<b>2 367</b>	<b>2 708</b>	<b>389</b>	<b>-732</b>	<b>2 734</b>
Financial income and expenses	-417	390	-287	97	259
<b>Income after financial items</b>	<b>1 950</b>	<b>3 098</b>	<b>102</b>	<b>-635</b>	<b>2 993</b>
Taxes	-1 256	-1 017	-453	82	-1 492
<b>Net income</b>	<b>694</b>	<b>2 081</b>	<b>-351</b>	<b>-553</b>	<b>1 501</b>
<b>Attributable to</b>					
Parent Company's shareholders	694	2 099	-351	-535	1 501
Non-controlling interests	-	-18	-	-18	-
	<b>694</b>	<b>2 081</b>	<b>-351</b>	<b>-553</b>	<b>1 501</b>
Earnings per share, SEK	0,03	0,09	-0,01	-0,02	0,07
Earnings per share, SEK*	0,03	0,09	-0,01	-0,02	0,07
Average number of outstanding shares	25 190 086	22 385 583	26 190 496	23 609 412	22 567 807
Average number of outstanding shares*	25 457 234	22 600 583	26 402 496	23 824 412	22 782 807
Number of shares at closing day	26 190 496	23 614 088	26 190 496	23 614 088	23 614 088
Number of shares at closing day*	26 402 496	23 829 088	26 402 496	23 829 088	23 829 088
<b>EBITDA</b>	<b>13 438</b>	<b>12 366</b>	<b>4 077</b>	<b>2 737</b>	<b>15 952</b>
Amortization	-7 903	-7 739	-2 631	-2 628	-10 357
Depreciation	-3 168	-1 919	-1 057	-841	-2 861
<b>Operating income</b>	<b>2 367</b>	<b>2 708</b>	<b>389</b>	<b>-732</b>	<b>2 734</b>

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

## CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME

SEK THOUSANDS	January - September		July - September		Whole year
	2017	2016	2017	2016	2016
<b>Net income</b>	<b>694</b>	<b>2 081</b>	<b>-351</b>	<b>-553</b>	<b>1 501</b>
<b>Other comprehensive income</b>					
<i>Items that may be reclassified to the income statement</i>					
Exchange rate differences	-5 696	2 072	-2 276	847	4 658
Tax attributable to items that have been transferred, or can be transferred to net income	491	-227	210	-71	-457
<b>Total other comprehensive income, net after tax</b>	<b>-5 205</b>	<b>1 845</b>	<b>-2 066</b>	<b>776</b>	<b>4 201</b>
<b>Total comprehensive income</b>	<b>-4 511</b>	<b>3 926</b>	<b>-2 417</b>	<b>223</b>	<b>5 702</b>
<b>Attributable to</b>					
Parent Company's shareholders	-4 511	3 944	-2 417	241	5 702
Non-controlling interests	-	-18	-	-18	-
	<b>-4 511</b>	<b>3 926</b>	<b>-2 417</b>	<b>223</b>	<b>5 702</b>

# CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK THOUSANDS	September 30, 2017	September 30, 2016	Dec 31, 2016
<b>ASSETS</b>			
Goodwill	65 216	65 451	65 672
Other intangible fixed assets	170 242	155 235	158 073
Property, plant and equipment	13 239	13 758	15 166
Financial assets	14 173	13 697	12 281
<b>Total non-current assets</b>	<b>262 870</b>	<b>248 141</b>	<b>251 192</b>
Inventories	32 169	32 046	34 551
Current receivables	32 515	26 560	38 684
Liquid funds	200 818	40 053	24 871
<b>Total current assets</b>	<b>265 502</b>	<b>98 659</b>	<b>98 106</b>
<b>Total assets</b>	<b>528 372</b>	<b>346 800</b>	<b>349 298</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
Shareholders' equity, attributable to the Parent Company's shareholders	498 188	314 406	316 414
Shareholders' equity, attributable to Non-controlling interests	-	1 805	-
Long-term non-interest-bearing liabilities	3 196	3 857	3 044
Short-term non-interest-bearing liabilities	26 988	26 732	29 840
<b>Total shareholders' equity and liabilities</b>	<b>528 372</b>	<b>346 800</b>	<b>349 298</b>

## CONSOLIDATED KEY RATIOS

	January - September		July - September		Whole year 2016
	2017	2016	2017	2016	
Gross margin non-Durable goods, %	79	80	78	80	80
Gross margin, %	76	74	78	76	74
EBITDA, %	13	12	13	9	12
Operating margin, %	2	3	1	-2	2
Net margin, %	1	2	-1	-2	1
Equity/assets ratio, %	94	91	94	91	91
Income per share, SEK	0,03	0,09	-0,01	-0,02	0,07
Shareholders' equity per share, SEK	19,02	13,31	19,02	13,31	13,40
Share price on closing day, SEK	94,75	75,75	94,75	75,75	88,00

See page 15-16 for key ratios definition and reconciliation of alternative key figures.

## CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK THOUSANDS	January - September		July - September		Whole year
	2017	2016	2017	2016	
Income after financial items	1 950	3 098	102	-635	2 993
Adjustment for items not affecting cash flow	9 516	10 103	3 319	4 450	14 727
Paid taxes	-4 417	-4 406	-1 255	-1 907	-4 528
Change in inventories	-1 125	-1 743	-399	-4 196	-2 379
Change in trade receivables	7 692	3 597	3 121	2 019	-8 219
Change in trade payables	686	8 060	2 710	5 632	9 956
<b>Cash flow from operating activities</b>	<b>14 302</b>	<b>18 709</b>	<b>7 598</b>	<b>5 363</b>	<b>12 550</b>
Cash flow from investing activities	-22 006	-20 351	-9 339	-7 593	-29 725
Cash flow from financing activities	184 765	244	-58	-	244
<b>Cash flow for the period</b>	<b>177 061</b>	<b>-1 398</b>	<b>-1 799</b>	<b>-2 230</b>	<b>-16 931</b>
Liquid funds at beginning of period	24 871	41 234	203 040	41 779	41 234
Exchange rate difference in liquid funds	-1 114	217	-423	504	568
<b>Liquid funds at end of period</b>	<b>200 818</b>	<b>40 053</b>	<b>200 818</b>	<b>40 053</b>	<b>24 871</b>

## CONSOLIDATED CHANGES IN SHAREHOLDERS EQUITY

SEK THOUSANDS	Attributable to Parent Company's shareholders				Non-controlling interests	Sum shareholders' equity
	Share capital	Other paid in capital	Reserves	Retained earnings incl. profit for the year		
<b>Shareholders' equity as of 1 January, 2016</b>	<b>550</b>	<b>154 567</b>	<b>9 140</b>	<b>20 617</b>	<b>0</b>	<b>184 874</b>
Total comprehensive income Jan - September, 2016			1 845	2 099	-18	3 926
Share warrant program		244				244
Acquisition of subsidiary	51	121 099			7 426	128 576
Acquisition from non-controlling interest	3	5 235		-323	-5 603	-688
Deduction of incremental costs directly related to issuing new shares		-721				-721
<b>Shareholders' equity as of 30 September, 2016</b>	<b>604</b>	<b>280 424</b>	<b>10 985</b>	<b>22 393</b>	<b>1 805</b>	<b>316 211</b>
Total comprehensive income October - December, 2016			2 356	-598	18	1 776
Acquisition from non-controlling interest		308		-216	-1 823	-1 731
Deduction of incremental costs directly related to issuing new shares net of tax		158				158
<b>Shareholders' equity as of 31 December, 2016</b>	<b>604</b>	<b>280 890</b>	<b>13 341</b>	<b>21 579</b>	<b>0</b>	<b>316 414</b>
Total comprehensive income Jan - September, 2017			-5 205	694		-4 511
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	66	186 391				186 457
Paid in capital for share warrant program		347				347
Acquisition from non-controlling interest					-519	-519
<b>Shareholders' equity as of 30 September, 2017</b>	<b>670</b>	<b>467 628</b>	<b>8 136</b>	<b>22 273</b>	<b>-519</b>	<b>498 188</b>

## CONDENSED CONSOLIDATED STATEMENT OF NET INCOME PER QUARTER

SEK THOUSANDS	Jul - Sep 2017	Apr - Jun 2017	Jan - Mar 2017	Oct - Dec 2016	Jul - Sep 2016	Apr - Jun 2016	Jan - Mar 2016	Oct - Dec 2015
Net sales	32 263	37 034	37 477	38 418	31 730	34 498	33 531	32 680
Cost of goods sold	-7 004	-7 823	-10 388	-9 530	-7 494	-9 639	-9 279	-8 055
<b>Gross income</b>	<b>25 259</b>	<b>29 211</b>	<b>27 089</b>	<b>28 888</b>	<b>24 236</b>	<b>24 859</b>	<b>24 252</b>	<b>24 625</b>
Selling expenses	-10 384	-11 128	-11 371	-10 312	-9 770	-8 105	-7 521	-9 095
Administrative expenses	-4 662	-4 935	-5 057	-6 751	-5 418	-5 883	-6 437	-3 384
Research and development costs	-8 883	-10 537	-9 928	-11 028	-9 033	-8 651	-7 958	-7 877
Other operating revenues and expenses	-941	-646	-720	-771	-747	-556	-560	-475
<b>Operating income</b>	<b>389</b>	<b>1 965</b>	<b>13</b>	<b>26</b>	<b>-732</b>	<b>1 664</b>	<b>1 776</b>	<b>3 794</b>
Financial income and expenses	-287	-79	-51	-131	97	365	-72	-122
<b>Income after financial items</b>	<b>102</b>	<b>1 886</b>	<b>-38</b>	<b>-105</b>	<b>-635</b>	<b>2 029</b>	<b>1 704</b>	<b>3 672</b>
Taxes	-453	-796	-7	-475	82	-509	-590	-874
<b>Net income</b>	<b>-351</b>	<b>1 090</b>	<b>-45</b>	<b>-580</b>	<b>-553</b>	<b>1 520</b>	<b>1 114</b>	<b>2 798</b>
<b>Attributable to</b>								
Parent Company's shareholders	-351	1 090	-45	-580	-535	1 520	1 114	2 798
Non-controlling interests	-	-	-	-	-18	-	-	-
	<b>-351</b>	<b>1 090</b>	<b>-45</b>	<b>-580</b>	<b>-553</b>	<b>1 520</b>	<b>1 114</b>	<b>2 798</b>
Earnings per share, SEK	-0,01	0,04	0,00	-0,02	-0,02	0,07	0,05	0,13
Earnings per share, SEK*	-0,01	0,04	0,00	-0,02	-0,02	0,07	0,05	0,13
Average number of outstanding shares	26 190 496	25 765 673	23 614 088	23 614 088	23 609 412	21 534 958	21 512 769	21 512 769
Average number of outstanding shares*	26 402 496	26 140 117	23 829 089	23 829 089	23 824 412	21 534 958	21 512 769	21 512 769
Number of shares at closing day	26 190 496	26 190 496	23 614 088	23 614 088	23 614 088	23 531 941	21 512 769	21 512 769
Number of shares at closing day*	26 402 496	26 402 496	23 829 089	23 829 089	23 829 089	23 531 941	21 512 769	21 512 769
<b>EBITDA</b>	<b>4 077</b>	<b>5 685</b>	<b>3 676</b>	<b>3 586</b>	<b>2 737</b>	<b>4 759</b>	<b>4 870</b>	<b>6 881</b>
Amortization	-2 631	-2 626	-2 646	-2 618	-2 628	-2 558	-2 553	-2 504
Depreciation	-1 057	-1 094	-1 017	-942	-841	-537	-541	-583
<b>Operating income</b>	<b>389</b>	<b>1 965</b>	<b>13</b>	<b>26</b>	<b>-732</b>	<b>1 664</b>	<b>1 776</b>	<b>3 794</b>

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

## CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME PER QUARTER

SEK THOUSANDS	Jul - Sep 2017	Apr - Jun 2017	Jan - Mar 2017	Oct - Dec 2016	Jul - Sep 2016	Apr - Jun 2016	Jan - Mar 2016	Oct - Dec 2015
<b>Net income</b>	<b>-351</b>	<b>1 090</b>	<b>-45</b>	<b>-580</b>	<b>-553</b>	<b>1 520</b>	<b>1 114</b>	<b>2 798</b>
<b>Other comprehensive income</b> <i>Items that may be reclassified to the income statement</i>								
Exchange rate differences	-2 276	-2 686	-735	2 586	847	2 285	-1 060	-182
Tax attributable to items that have been transferred, or can be transferred to net income	210	245	36	-230	-71	-225	69	19
<b>Total other comprehensive income, net after tax</b>	<b>-2 066</b>	<b>-2 441</b>	<b>-699</b>	<b>2 356</b>	<b>776</b>	<b>2 060</b>	<b>-991</b>	<b>-163</b>
<b>Total comprehensive income</b>	<b>-2 417</b>	<b>-1 351</b>	<b>-744</b>	<b>1 776</b>	<b>223</b>	<b>3 580</b>	<b>123</b>	<b>2 635</b>
<b>Attributable to</b>								
Parent Company's shareholders	-2 417	-1 351	-744	1 776	241	3 580	123	2 635
Non-controlling interests	-	-	-	-	-18	-	-	-
	<b>-2 417</b>	<b>-1 351</b>	<b>-744</b>	<b>1 776</b>	<b>223</b>	<b>3 580</b>	<b>123</b>	<b>2 635</b>

## CONDENSED INCOME STATEMENT FOR THE PARENT COMPANY

SEK THOUSANDS	January - September		July - September		Whole year 2016
	2017	2016	2017	2016	
Net sales	87 685	64 772	31 982	24 759	85 719
Cost of goods sold	-21 216	-15 359	-6 817	-5 098	-20 648
<b>Gross income</b>	<b>66 469</b>	<b>49 413</b>	<b>25 164</b>	<b>19 661</b>	<b>65 071</b>
Selling expenses	-18 826	-13 640	-5 172	-4 890	-17 996
Administrative expenses	-8 380	-12 436	-2 082	-3 360	-17 514
Research and development costs	-29 348	-24 590	-8 899	-7 981	-35 144
Other operating revenues and expenses	-2 844	-1 786	-1 164	-710	-3 174
<b>Operating income</b>	<b>7 071</b>	<b>-3 039</b>	<b>7 847</b>	<b>2 720</b>	<b>-8 757</b>
Financial income and expenses	-2 064	1 443	-1 058	431	2 839
<b>Income after financial items</b>	<b>5 007</b>	<b>-1 596</b>	<b>6 789</b>	<b>3 151</b>	<b>-5 918</b>
Year end dispositions	-	-	-	-	4 025
Taxes	-1 102	-294	-1 494	-497	101
<b>Net income</b>	<b>3 905</b>	<b>-1 890</b>	<b>5 295</b>	<b>2 654</b>	<b>-1 792</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 9 923 thousand (9 148), of which SEK 3 895 TSEK (3 120) for the quarter.

## CONDENSED BALANCE SHEET FOR THE PARENT COMPANY

SEK THOUSANDS	September 30, 2017	September 30, 2016	Dec 31, 2016
<b>ASSETS</b>			
Intangible fixed assets	105 057	91 085	92 827
Property, plant and equipment	9 889	10 309	11 501
Financial assets	196 564	167 178	179 451
<b>Total non-current assets</b>	<b>311 510</b>	<b>268 572</b>	<b>283 779</b>
Inventories	6 959	10 461	13 521
Current receivables	16 785	19 731	15 472
Cash and bank	184 662	28 142	13 730
<b>Total current assets</b>	<b>208 406</b>	<b>58 334</b>	<b>42 723</b>
<b>Total assets</b>	<b>519 916</b>	<b>326 906</b>	<b>326 502</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
Shareholders' equity	488 247	297 169	297 426
Untaxed reserves	8 213	12 238	8 213
Provisions	7 114	1 164	1 237
Short-term non-interest-bearing liabilities	16 342	16 335	19 626
<b>Total shareholders' equity and liabilities</b>	<b>519 916</b>	<b>326 906</b>	<b>326 502</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.

IFRS 9 "Financial instruments" will replace the current IAS 39 "Financial instruments: Recognition and Measurement" as of 2018. The implementation project is ongoing during 2017. To judge from the information that is today known or estimated, IFRS 9 will not have a material impact on XVIVO Perfusion's results and financial position.

IFRS 15 "Revenue from Contracts with Customers" will as of 2018 replace existing IFRS related to revenue recognition, such as IAS 18 "Revenue", IAS 11 "Construction Contracts" and IFRIC 13 "Customer Loyalty Programmes". XVIVO Perfusion has been able to ascertain that the company's financial reports will be impacted when IFRS 15 begins to be applied. The company's net sales are divided into three categories: sale of goods excluding capital goods, revenues from sale and rental of capital goods and finally revenues from freight, service and other sales (see note 2 in the company's most recent Annual Report). Sale of goods excluding capital goods and revenues from freight, service and other sales comprise products and services that clearly represent separate performance obligations. It is therefore assessed that for these there are not any significant differences between current accounting and accounting pursuant to IFRS 15. For revenues from sale and rental of capital goods, which comprised 11% of the company's net sales in 2016, and 5% of the company's net sales for the period January to September 2017, there may be several distinct commitments in one and the same contract. The income statement for some of these commitments may need to be postponed in accordance with IFRS 15 compared with current accounting. Since only 5% of net sales for the period January to September 2017 are affected and the shift in time is estimated to be one to two quarters, the amount of IFRS 15 estimates that can be estimated to be small for the period may be estimated.

IFRS 16 "Leases" will as of 2019 replace existing IFRS related to the recognition of leasing agreements, such as IAS 17 "Leases" and IFRIC 4 "Determining Whether an Arrangement Contains a Lease". XVIVO Perfusion has not yet decided whether to apply IFRS 16 in advance as from 2018, at the same time as IFRS 9 and IFRS 15 change the accounting, or whether to apply it from 2019. As an operational lessee, the company will be impacted by the introduction of IFRS 16. Estimates in terms of figures of the effect of IFRS 16 and the choice of transitional methods have not yet been made. However, the information given in Note 10 of the company's most recent Annual Report gives an indication of the type and scope of the agreements that existed at December 31, 2016. No new operational leasing agreements involving significant amounts were entered into in the first half of 2017.

XVIVO Perfusion has not yet decided whether IFRS 16 will be applied in advance as from 2018, at the same time as IFRS 9 and IFRS 15 change the financial reporting, or whether it will be applied as of 2019. As an operational lessee, XVIVO Perfusion will be impacted by the introduction of IFRS 16. Estimates of the impact of IFRS 16 in terms of figures and the choice of transition methods have not yet been made.

No new or revised accounting policies that became effective in 2017 have had any significant impact on the Group.

## Note 2. Share warrant programs

The 2017 annual shareholder meeting in XVIVO Perfusion AB approved the warrant program of a maximum of 243,000 warrants (equivalent to 243,000 shares) to be offered to employees in XVIVO Perfusion group. As of June 30, 2017 a total of 198,000 warrants were subscribed and paid for by employees.

In total there are 455,000 outstanding warrants in two programs. If all the warrants are exercised to subscribe for shares, the share capital will increase by around SEK 12,000 and the number of shares will increase by 455,000 shares in total, corresponding to dilution of approximately 1.7 percent of the total number of shares and votes. Share warrant program 2016/2018 consists of 212,000 warrants and in June 2018 each warrant will entitle the holder to subscribe for one new share at a price of SEK 90.22. Share warrant program 2017/2019 consists of 243,000 warrants and in the period May-June 2019 each warrant will entitle the holder to subscribe for one new share at a price of SEK 138.51.

## Note 3. Financial data per segment, group

SEK THOUSANDS	January - September					
	Net sales of non-Durable goods		Durable goods		Total consolidated	
	2017	2016	2017	2016	2017	2016
Net sales	101 552	87 975	5 222	11 784	106 774	99 759
Cost of goods sold	-21 496	-17 862	-3 719	-8 550	-25 215	-26 412
<b>Gross income</b>	<b>80 056</b>	<b>70 113</b>	<b>1 503</b>	<b>3 234</b>	<b>81 559</b>	<b>73 347</b>

SEK THOUSANDS	July - September					
	Net sales of non-Durable goods		Durable goods		Total consolidated	
	2017	2016	2017	2016	2017	2016
Net sales	31 573	29 140	689	2 590	32 262	31 730
Cost of goods sold	-7 004	-5 738	1	-1 756	-7 003	-7 494
<b>Gross income</b>	<b>24 569</b>	<b>23 402</b>	<b>690</b>	<b>834</b>	<b>25 259</b>	<b>24 236</b>

## Note 4. Financial instruments

The Group's financial assets and liabilities valued at acquisition value amount to SEK 228 (62) million and SEK 24 (27) 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	Jan - Sep		Jul - Sep		Whole year 2016
	2017	2016	2017	2016	
<b>Operating income</b>	<b>2 367</b>	<b>2 708</b>	<b>389</b>	<b>-732</b>	<b>2 734</b>
Amortization	7 903	7 739	2 631	2 628	10 357
Depreciation	3 168	1 919	1 057	841	2 861
<b>EBITDA</b>	<b>13 438</b>	<b>12 366</b>	<b>4 077</b>	<b>2 737</b>	<b>15 952</b>

## Gross margin

SEK THOUSANDS	Jan - Sep 2017		Jul - Sep 2017		2016	Whole year 2016
Operating income						
Net sales	106 774	99 759	32 263	31 730	138 177	
Operating expenses						
Cost of goods sold	-25 215	-26 412	-7 004	-7 494	-35 942	
<b>Gross income</b>	<b>81 559</b>	<b>73 347</b>	<b>25 259</b>	<b>24 236</b>	<b>102 235</b>	
<b>Gross margin %</b>	<b>76</b>	<b>74</b>	<b>78</b>	<b>76</b>	<b>74</b>	

## Gross margin non-Durable goods

SEK THOUSANDS	Jan - Sep 2017		Jul - Sep 2017		2016	Whole year 2016
Operating income						
Net sales of non-Durable goods	101 552	87 975	31 573	29 140	122 527	
Operating expenses						
Cost of non-Durable goods sold	-21 496	-17 862	-7 004	-5 738	-24 798	
<b>Gross income, non-Durable goods</b>	<b>80 056</b>	<b>70 113</b>	<b>24 569</b>	<b>23 402</b>	<b>97 729</b>	
<b>Gross margin, non-Durable goods %</b>	<b>79</b>	<b>80</b>	<b>78</b>	<b>80</b>	<b>80</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	Sep 30, 2017	Sep 30, 2016	Dec 31, 2016
Shareholders' equity	498 188	316 211	316 414
Total assets	528 372	346 800	349 298
<b>Equity/assets ratio %</b>	<b>94</b>	<b>91</b>	<b>91</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.

## KEY RATIOS DEFINITION

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 4,000 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.

# XVIVO PERFUSIONS PRODUCTS

WARM PERFUSION	WARM PERFUSION	ACCESSORIES	COLD PERFUSION
 <p>XPST™, Durable goods</p>  <p>XPS Disposable Kit™</p>	 <p>LS™, Durable goods</p>  <p>LS Disposable Kit™</p>	 <p>STEEN Solution™</p>  <p>XVIVO Organ Chamber™</p>  <p>XVIVO Lung Cannula Set™</p>	 <p>PERFADEX®</p>  <p>Silicone Tubing Set™</p>



[WWW.XVIVOPERFUSION.COM](http://WWW.XVIVOPERFUSION.COM)

XVIVO Perfusion AB (publ), Box 53015, SE-400 14 Göteborg. Tel: +46 31-788 21 50. Fax: +46 31-788 21 69.  
XVIVO Perfusion Inc., 3666 South Inca Street, Englewood, CO 80110, USA, Tel: +1 303 395 9171, Fax +1 800 694 5897.  
XVIVO Perfusion Lund AB, Propellervägen 16, SE-224 78 Lund, Sweden. Tel: +46 46 261 05 50. Fax: +46 31-788 21 69.