



# INTERIM REPORT JANUARY–SEPTEMBER 2018 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 marginal lungs. XVIVO Perfusion employs around 40 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 SALES GROWTH DRIVEN BY WARM PERFUSION

## THIRD QUARTER 2018 (JUL - SEP)

- Total net sales in the quarter amounted to SEK 40.9 (32.3) million, corresponding to an increase of 27 percent. The increase corresponds to 18 percent in local currency. Net sales of non-durable goods in the quarter amounted to SEK 40.3 (31.6) million, corresponding to an increase of 27 percent in SEK. Sales of non-durable goods increased by 18 percent in local currency.
- Sales from warm perfusion\* showed a growth record of more than 60 percent during the quarter. Sales from warm perfusion represented 40 percent (30) of sales of non-durable goods.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 5.2 (4.1) million, corresponding to an EBITDA margin of 13 percent. In comparison the operating income before depreciation and amortization (EBITDA) for the same quarter 2017, excluding items affecting comparability, amounted to SEK 4.4 million, corresponding to an EBITDA margin, excluding items affecting comparability, of 14 percent.
- Operating income amounted to SEK 0.7 (0.4) million, after amortization and depreciation of SEK 4.5 (3.7) million.
- Net income amounted to SEK 0.1 (-0.4) million, resulting in earnings per share of SEK 0.00 (-0.01).
- Cash flow from operating activities was SEK 3.7 (7.6) million.
- Perfadex Plus, an improved version of Perfadex, has been launched in the USA
- XVIVO's new prototype of a heart preservation machine has been pre-clinically tested with good results.

## THE PERIOD 2018 (JAN - SEP)

- Total net sales amounted to SEK 129.5 (106.8) million, corresponding to an increase of 21 percent. The increase corresponds to 19 percent in local currency. Net sales of non-durable goods for the period amounted to SEK 120.4 (101.6) million, corresponding to an increase of 19 percent in SEK. Sales of non-durable goods increased by 16 percent in local currency.
- Sales from warm perfusion\* represented 40 percent (32) of sales of non-durable goods.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 20.4 (13.4) million, corresponding to an EBITDA margin of 16 percent. In comparison the operating income before depreciation and amortization (EBITDA) for the same period 2017, excluding items affecting comparability, amounted to SEK 15.7 million, corresponding to an EBITDA margin, excluding items affecting comparability, of 15 percent.
- Operating income amounted to SEK 7.9 (2.4) million, after amortization and depreciation of SEK 12.6 (11.1) million.
- Net income amounted to SEK 7.8 (0.7) million, resulting in earnings per share of SEK 0.30 (0.03).
- Cash flow from operating activities was SEK 26.0 (14.3) million.
- PMA application for STEEN Solution™ and XPST™ was filed with the FDA.
- Perfadex Plus, an upgraded version of Perfadex, has been launched in Europe and the USA.
- Analysis of the PrimECC®-study showed that the product is safe and showed positive clinical results.
- United Therapeutics and XVIVO Perfusion initiated a collaboration and United Therapeutics intends to use XVIVO Perfusion's products in their organ assessment services.
- SEK 19 million share issue as a result of warrants being exercised.
- Reimbursement codes (so called CPT codes) have been valid in the USA since 1 January, 2018. The new codes simplify the reimbursement process for hospitals on the American market.
- 4 XPST™ were delivered during the period. At the end of the period 47 hospitals had access to either XPST™ or LS™.

## CONFERENCE CALL

CEO Magnus Nilsson will present the report in a conference call at 2 p.m. CET on Friday, October 26, 2018.  
Telephone UK: +44 (0) 3333 0008 04 or USA: +1 631 913 1422, enter code 83059919#.

## MILESTONES PASSED DURING THE THIRD QUARTER

Pefadex Plus has been launched in the USA. The product is an improved ready to use version of Perfadex which simplifies usage and increases safety.

XVIVO's new prototype of a heart preservation machine has been pre-clinically tested with good results

### CEO'S COMMENTS



The third quarter was both eventful and positive for XVIVO Perfusion. Several of the company's most important priority product development projects have taken important steps in the right direction. In parallel, the company continues to experience a good growth rate, while maintaining a healthy gross

margin and positive EBITDA.

XVIVO Perfusion's launch of products for lung transplantation is progressing successfully and according to plan. Sales growth of non-durable goods was +18 percent in local currency during the third quarter. We are particularly pleased that consumable products for warm perfusion (revenue excluding machines) accounted for almost half of the increase in sales. Sales from warm perfusion showed a growth record of more than 60 percent during the quarter.

The company has a good dialogue with the FDA concerning the PMA application for STEEN Solution™ and XPS™ that was submitted during the second quarter. The FDA has also performed most of the compulsory reviews required before approval. The company has had HDE approval (Humanitarian Device Exemption) since 2014 and already markets the products in the US. However, HDE approval entails certain restrictions and PMA approval which would mean that these restrictions would cease to exist facilitating the clinics' reimbursement process.

The interesting results from the PrimECC study at Sahlgrenska University Hospital have enabled the company to continue the work of extending the documentation of PrimECC. Multi-center studies are now being prepared to

focus on the observed positive clinical effects under better statistical conditions. The company has also received a very good response from those clinics wishing to participate. It is planned that the studies will start just before or right after New Year.

Significant progress has been made with the company's high-priority heart transplant project. The most important points to highlight are the preclinical trials with the new commercial version of the machine, the development of input products tailor-made for the machine and product development of the heart solution. At the same time preparations are ongoing for the multicenter study that it is estimated to begin during the first quarter of 2019. The group of clinics that will lead this groundbreaking study on the preservation of the heart during transportation has already received training from Professor Stig Steen at his Igelösa research center near Lund.

The lung transplantation business area is focusing both on increasing the installation base of the company's EVLP (Ex Vivo Lung Perfusion) machines and on supporting centers that have these machines with technical and practical expertise. The main focus has been, and will continue to be, assuring sufficient resources are directed for training and service at these clinics. The company will also continue to develop the EVLP technology in order to support the transplantation surgeons in their efforts to treat more of the patients on waiting lists. XVIVO's research focuses on continuing to lead the development of innovative solutions in the field of thorax surgery and on developing the use of perfusion for more organs in transplantation. The company also conducts research into the use of the same technology to treat isolated organs and tissue still in the body.

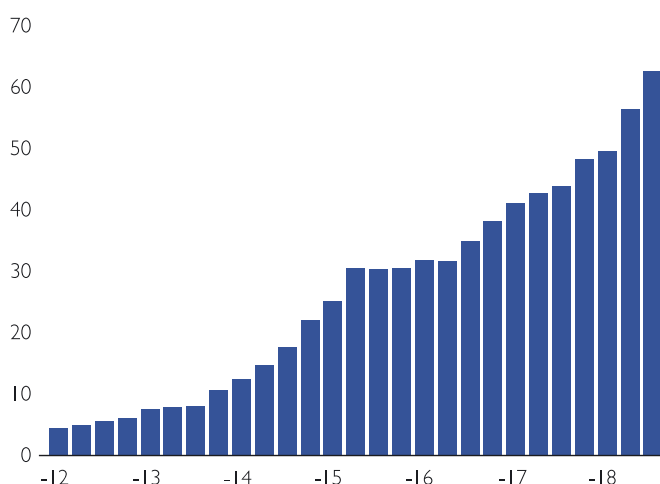
Magnus Nilsson  
CEO

## THIRD QUARTER 2018 (JULY - SEPTEMBER)

### Net Sales

Total net sales in the quarter amounted to SEK 40.9 (32.3) million, corresponding to an increase of 27 percent in SEK and 18 percent in local currency.

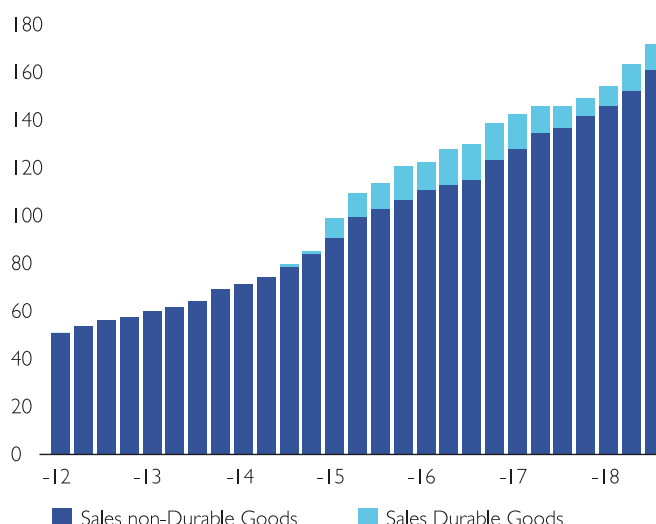
#### NET SALES WARM PERFUSION EXCL. DURABLE GOODS ROLLING 12-MONTHS (SEK MILLIONS)



percent in local currency. XVIVO Perfusion's net sales of non-durable goods\* in the quarter amounted to SEK 40.3 (31.6) million, corresponding to an increase of 27 percent in SEK and 18 percent in local currency.

Sales from warm perfusion showed a growth record of more than 60 percent during the quarter. Total sales from warm

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



## COMPILATION OF NET SALES AND EBITDA

SEK THOUSANDS	January - September		July - September		Whole year
	2018	2017	2018	2017	2017
Net Sales non-Durable Goods	120 360	101 552	40 251	31 573	140 994
Net Sales Durable Goods	9 119	5 222	663	690	7 348
<b>Net Sales Total</b>	<b>129 479</b>	<b>106 774</b>	<b>40 914</b>	<b>32 263</b>	<b>148 342</b>
Cost of Goods non-Durable Goods	-27 885	-21 496	-9 413	-7 004	-30 362
Cost of Goods Durable goods	-7 415	-3 719	-463	-	-4 584
Cost of Goods Total	-35 300	-25 215	-9 876	-7 004	-34 946
Gross income non-Durable Goods	92 475	80 056	30 838	24 569	110 632
Gross margin non-Durable Goods, %	77%	79%	77%	78%	78%
Gross income Durable Goods	1 704	1 503	200	690	2 764
Gross income Total	94 179	81 559	31 038	25 259	113 396
Gross margin Total, %	73%	76%	76%	78%	76%
Selling expenses	-33 782	-32 883	-11 846	-10 384	-43 702
Administrative expenses	-14 711	-14 654	-5 513	-4 662	-20 045
Research and development costs	-35 371	-29 348	-11 734	-8 883	-39 469
Other operating revenues and expenses	-2 429	-2 307	-1 207	-941	-3 074
<b>Operating Income</b>	<b>7 886</b>	<b>2 367</b>	<b>738</b>	<b>389</b>	<b>7 106</b>
Depreciation and amortization of cost of goods sold	-350	-367	-151	-98	-385
Depreciation and amortization of administrative expenses	-1 036	-607	-502	-227	-985
Depreciation of research and development expenses	-8 163	-7 913	-2 749	-2 638	-10 559
Depreciation and amortization of other operative expenses	-3 003	-2 184	-1 067	-725	-2 987
<b>EBITDA</b>	<b>20 438</b>	<b>13 438</b>	<b>5 207</b>	<b>4 077</b>	<b>22 022</b>
EBITDA, %	16%	13%	13%	13%	15%
Items affecting comparability**	-	-2 280	-	-365	-2 802
EBITDA excluding items affecting comparability	20 438	15 718	5 207	4 442	24 824
EBITDA excluding items affecting comparability, %	16%	15%	13%	14%	17%

perfusion (STEEN Solution™, XPS™, LS™, and products and services related to the use of the XPS™ and LS™) accounted for 41 (32) 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 40 (30) percent of the total sales of non-durable goods.

## Income

Operating income before depreciation and amortization (EBITDA) amounted to SEK 5.2 (4.1) million, corresponding to an EBITDA margin of 13 percent. In comparison the operating income before depreciation and amortization (EBITDA) for the same quarter 2017, excluding items affecting comparability, amounted to SEK 4.4 million, corresponding to an EBITDA margin, excluding items affecting comparability, of 14 percent.

Operating income amounted to SEK 0.7 (0.4) million, after amortization and depreciation of SEK 4.5 (3.7) million.

The gross margin for non-durable goods during the quarter was 77 (78) percent. The decrease against the comparable quarter is mainly attributable to changes in product mix. The total gross margin during the quarter was 76 (78) percent. The decrease is mainly attributable to changes in segment mix.

Selling expenses in relation to sales decreased during the quarter to 29 (32) percent. The decrease is primarily attributable to scale advantages. R&D expenses amounted to 29 (28) percent of sales. Administrative expenses decreased to 13 (14) percent of sales, mainly due to extraordinary costs affecting comparability during 2017. Net other operating revenues and expenses during the quarter were SEK -1.2 (-0.9) million.

During the quarter, SEK 10.3 (7.4) million of the development costs were capitalized as an intangible asset. SEK 3.1 (4.2) million was attributable to the continued NOVEL study with STEEN Solution™ and XPS™ with the aim of PMA approval. SEK 6.6 (2.9) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, and SEK 0.6 (0.2) million was attributable to product development of the rest of the product portfolio. Depreciation and amortization for the quarter amounted to SEK 2.5 (2.4) million, of which SEK 2.5 (2.4) million was amortization of the HDE approval.

## Cash flow

Cash flow from operating activities amounted to SEK 3.7 (7.6). The main reason for the decrease compared to the same period prior year is that investments in inventory have been made to meet increased sales forecasts for warm perfusion and due to the launch of Perfadex Plus. Investments amounted to SEK 11.3 (9.3) million, whereof SEK 10.3 (8.0) million was invested in intangible assets and SEK 1.0 (1.3) million was invested in tangible assets. Cash and cash equivalents at the end of the quarter amounted to SEK 201.3 (200.8) million.

# THE PERIOD 2018 (JANUARY - SEPTEMBER)

## Net Sales

Total net sales in the period amounted to SEK 129.5 (106.8) million, corresponding to an increase of 21 percent in SEK and 19 percent in local currency. XVIVO Perfusion's net sales of non-durable goods\* in the period amounted to SEK 120.4 (101.6) million, corresponding to an increase of 19 percent in SEK and 16 percent in local currency.

Total sales from warm perfusion (STEEN Solution™, XPS™, LS™, and products and services related to the use of the XPS™ and LS™) accounted for 44 (36) 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 40 (32) percent of the total sales of non-durable goods.

## Income

Operating income before depreciation and amortization (EBITDA) amounted to SEK 20.4 (13.4) million, corresponding to an EBITDA margin of 16 percent. In comparison the operating income before depreciation and amortization (EBITDA) for the same period 2017, excluding items affecting comparability, amounted to SEK 15.7 million, corresponding to an EBITDA margin, excluding items affecting comparability, of 15 percent.

Operating income amounted to SEK 7.9 (2.4) million, after amortization and depreciation of SEK 12.6 (11.1) million.

The gross margin for non-durable goods during the period was 77 (79) percent. The decrease against the comparable period is mainly attributable to changes in product mix. The total gross margin during the period was 73 (76) percent. The decrease is mainly attributable to changes in segment mix.

Selling expenses in relation to sales decreased during the period to 26 (31) percent. The decrease is primarily attributable to temporary vacancies in the sales organization during the first half of the year, but also scale advantages. R&D expenses amounted to 27 (27) percent of sales. Administrative expenses decreased to 11 (14) percent of sales, mainly due to extraordinary costs affecting comparability during 2017. Net other operating revenues and expenses during the period were SEK -2.4 (-2.3) million.

During the period, SEK 35.1 (19.4) millions of the development costs were capitalized as an intangible asset. SEK 16.2 (9.3) million was attributable to the continued NOVEL study with STEEN Solution™ and XPS™ with the aim of PMA approval. SEK 18.3 (9.2) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, and SEK 0.6 (0.9) million was attributable to product development of the product portfolio. Depreciation



and amortization for the period amounted to SEK 7.6 (7.5) million, of which SEK 7.5 (7.5) million was amortization of the HDE approval.

### **Cash flow**

Cash flow from operating activities amounted to SEK 26.0 (14.3). Investments amounted to SEK 41.3 (22.0) million, whereof SEK 35.7 (20.1) million was invested in intangible assets and SEK 5.6 (1.5) million was invested in tangible assets. The cash flow from financing activities was SEK 19.2 (184.8) million due to the issue of new shares related to a share warrant program. Cash and cash equivalents at the end of the quarter amounted to SEK 201.2 (200.8) million.

### **Financing**

XVIVO Perfusion's total credit facilities consist of an overdraft facility that at the end of the period amounted to SEK 30 (22) million, of which SEK 0.0 (0.0) million was utilized. The equity/assets ratio was 92 (94) percent at the end of the period.

### **PMA application for XPS™ with STEEN Solution™ submitted to the FDA**

During the second quarter, XVIVO Perfusion submitted the PMA (Premarket Approval) application for the XPS™ with STEEN Solution™ to the FDA. The submission of the PMA application was the goal of a six-year effort with the company's largest multicenter study ever performed. The NOVEL Extension Clinical trial, that completed enrollment of 220 (110 + 110) patients in 2017 constitutes the basis of the company's PMA application.

Around 40 percent of all lung transplants in the world are performed in the US. STEEN Solution™ and XPS™ are already approved for marketing in the US under a HDE (Humanitarian Device Exemption).

In March 2014, the FDA Advisory Panel voted unanimously 10-0 that the XPS™ System with STEEN Solution™ met the requirements for HDE (Humanitarian Device Exemption) approval by proving safety. In August 2014, XVIVO Perfusion received HDE approval from the FDA for the XPS™ with STEEN Solution™ for use in flushing and temporary continuous normothermic machine perfusion of initially unacceptable excised donor lungs during which time the ex-vivo function of the lungs can be reassessed for transplantation. HDE approval entails certain restrictions, amongst other things that no more than 8,000 patients may be treated per year under HDE approval and that separate institutional IRB approval may be required for treatment. A PMA will no longer entail any such restrictions.

### **Positive findings in the PrimECC study**

PrimECC® is a CE-marked and patent-protected product, developed to prime the heart-lung machine before open heart surgery. The PrimECC® study was completed during 2017 and

was performed at Sahlgrenska University Hospital. The study included 80 (40 +40) patients randomized to have the heart-lung machine primed with either PrimECC® or the conventional, simpler solution currently used at the hospital. Analysis of the results shows that the product is safe and indicates interesting findings regarding decreased side effects when using PrimECC®.

Several hundred thousand heart operations are performed in the world each year using a heart-lung machine. As expected the blind, randomized study conducted with PrimECC® at Sahlgrenska University Hospital gives patients a better fluid balance during and after the operation if the heart-lung machine has been primed with PrimECC®. The study also indicates a reduced risk of kidney damage. The results further verify that PrimECC® is a safe product to use. A surprising and positive effect is that the results from the study show that the use of PrimECC® also reduces red blood cell destruction, so-called hemolysis, which occurs when blood is circulated outside the body in a heart-lung machine. Hemolysis releases substances that are harmful to both kidneys and blood vessels and may be a problem during cardiovascular surgery. To expand the documentation and spread the use of PrimECC®, the company has decided on further studies.

### **XVIVO Perfusion launches Perfadex Plus, an upgraded version of Perfadex**

XVIVO Perfusion has spent nearly five years developing a ready to use version of its' product for cold preservation of lungs. The company has through formulation development upgraded the product so that it now can be used without prior addition and mixing of buffer and electrolyte. The new upgraded version of Perfadex is named Perfadex Plus and the company has filed for patent for Perfadex Plus. The product is CE marked and approved by the FDA (510k). It has been launched in European countries and in the USA and is expected to be available in all major markets within 12 months.

### **United Therapeutics and XVIVO Perfusion announced collaboration**

During the second quarter, Lung Bioengineering, a subsidiary of United Therapeutics, agreed to purchase multiple XVIVO Perfusion System (XPS™) machines from XVIVO Perfusion for use in its Silver Spring EVLP laboratory, while XVIVO Perfusion agreed to provide training. United Therapeutics will also purchase equipment for use of the machines to re-evaluate donated lungs that have initially been deemed unsuitable for transplant directly following explant from the donor. In addition, Lung Bioengineering and XVIVO Perfusion agreed to collaborate in promoting the use of EVLP services that could increase the supply of transplantable lungs to address needless patient deaths on the transplant waitlist. In the coming fourth quarter XVIVO plans to sell another XPS machine to Lung Bioengineering.

## **SEK 19 million share issue as a result of warrants being exercised**

As a result of warrants being exercised, the number of shares and votes in XVIVO Perfusion AB (publ) in June 2018 increased by 212.000 shares and votes. The share issue of 212.000 shares raised approximately SEK 19 million before issue costs.

## **OUTLOOK FOR 2018 AND 2019**

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 continue to develop the method with the aim of establishing the STEEN Solution™ method as the standard treatment for lung transplantation. The company will intensify clinical research and product development in cardiac transplantation. Expenses attributable to cardiac transplantation will be capitalized on an ongoing basis.

Organ availability is also the limiting factor for increasing the number of transplantations of organs other than lungs and hearts. 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 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, and are the only products to date to have received 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**

The center in Lund (Sweden) develops a machine and products for heart preservation. The products are designed to help 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 with better quality of life. The products are in the phase of pre-clinical studies and clinical proof of concept. Future focus is to take the products into the phase of 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 37, of whom 17 were women and 20 were men. Of these, 22 people were employed in Sweden and 15 outside Sweden. In addition, the company uses around 10 consultants.

### Information on transactions with related parties

During the quarter, one transaction with a related party has been conducted. The Board member Folke Nilsson was paid SEK 24 375 for consultancy services within the product development area.

### 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 2017 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 2019 Annual General Meeting

The following members have been appointed to XVIVO Perfusion's Nomination Committee for the 2019 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 April 25, 2019 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 26, 2018

The Board



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

**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 2018 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 26 October 2018

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 2018: Thursday, February 8, 2019  
Interim report January-March 2019: Wednesday, April 24, 2019  
Interim Report January-June 2019: Friday, July 12, 2019  
Interim Report January-September 2019: Thursday, October 24, 2019  
Report on Operations 2019: Thursday, February 6, 2020

**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 26, 2018 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
	2018	2017	2018	2017	2017
Net sales	129 479	106 774	40 914	32 263	148 342
Cost of goods sold	-35 300	-25 215	-9 876	-7 004	-34 946
<b>Gross income</b>	<b>94 179</b>	<b>81 559</b>	<b>31 038</b>	<b>25 259</b>	<b>113 396</b>
Selling expenses	-33 782	-32 883	-11 846	-10 384	-43 702
Administrative expenses	-14 711	-14 654	-5 513	-4 662	-20 045
Research and development costs	-35 371	-29 348	-11 734	-8 883	-39 469
Other operating revenues and expenses	-2 429	-2 307	-1 207	-941	-3 074
<b>Operating income</b>	<b>7 886</b>	<b>2 367</b>	<b>738</b>	<b>389</b>	<b>7 106</b>
Financial income and expenses	2 290	-417	-803	-287	346
<b>Income after financial items</b>	<b>10 176</b>	<b>1 950</b>	<b>-65</b>	<b>102</b>	<b>7 452</b>
Taxes	-2 376	-1 256	164	-453	-1 192
<b>Net income</b>	<b>7 800</b>	<b>694</b>	<b>99</b>	<b>-351</b>	<b>6 260</b>
<b>Attributable to</b>					
Parent Company's shareholders	7 800	694	99	-351	6 260
Non-controlling interests	-	-	-	-	-
	<b>7 800</b>	<b>694</b>	<b>99</b>	<b>-351</b>	<b>6 260</b>
Earnings per share, SEK	0,30	0,03	0,00	-0,01	0,25
Earnings per share, SEK*	0,30	0,03	0,00	-0,01	0,24
Average number of outstanding shares	26 269 015	25 190 086	26 402 496	26 190 496	25 440 188
Average number of outstanding shares*	26 397 015	25 457 234	26 786 496	26 402 496	25 693 549
Number of shares at closing day	26 402 496	26 190 496	26 402 496	26 190 496	26 190 496
Number of shares at closing day*	26 879 496	26 402 496	26 879 496	26 402 496	26 402 496
<b>EBITDA</b>	<b>20 438</b>	<b>13 438</b>	<b>5 207</b>	<b>4 077</b>	<b>22 023</b>
Amortization	-8 136	-7 903	-2 736	-2 631	-10 542
Depreciation	-4 416	-3 168	-1 733	-1 057	-4 375
<b>Operating income</b>	<b>7 886</b>	<b>2 367</b>	<b>738</b>	<b>389</b>	<b>7 106</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
	2018	2017	2018	2017	2017
<b>Net income</b>	<b>7 800</b>	<b>694</b>	<b>99</b>	<b>-351</b>	<b>6 260</b>
<b>Other comprehensive income</b>					
<i>Items that may be reclassified to the income statement</i>					
Exchange rate differences	3 749	-5 696	-801	-2 276	-5 187
Tax attributable to items that have been transferred, or can be transferred to net income	-309	491	81	210	464
<b>Total other comprehensive income, net after tax</b>	<b>3 440</b>	<b>-5 205</b>	<b>-720</b>	<b>-2 066</b>	<b>-4 723</b>
<b>Total comprehensive income</b>	<b>11 240</b>	<b>-4 511</b>	<b>-621</b>	<b>-2 417</b>	<b>1 537</b>
<b>Attributable to</b>					
Parent Company's shareholders	11 240	-4 511	-621	-2 417	1 537
Non-controlling interests	-	-	-	-	-
	<b>11 240</b>	<b>-4 511</b>	<b>-621</b>	<b>-2 417</b>	<b>1 537</b>

# CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK THOUSANDS	Sept 30, 2018	Sept 30, 2017	Dec 31, 2017
<b>ASSETS</b>			
Goodwill	65 561	65 216	65 273
Other intangible fixed assets	204 416	170 242	176 902
Property, plant and equipment	17 711	13 239	16 277
Financial assets	17 968	14 173	15 466
<b>Total non-current assets</b>	<b>305 656</b>	<b>262 870</b>	<b>273 918</b>
Inventories	36 145	32 169	30 703
Current receivables	35 697	32 515	38 597
Liquid funds	201 248	200 818	195 322
<b>Total current assets</b>	<b>273 090</b>	<b>265 502</b>	<b>264 622</b>
<b>Total assets</b>	<b>578 746</b>	<b>528 372</b>	<b>538 540</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
Shareholders' equity, attributable to the Parent Company's shareholders	534 630	498 188	504 332
Long-term non-interest-bearing liabilities	3 295	3 196	3 312
Short-term non-interest-bearing liabilities	40 821	26 988	30 896
<b>Total shareholders' equity and liabilities</b>	<b>578 746</b>	<b>528 372</b>	<b>538 540</b>

## CONSOLIDATED KEY RATIOS

	January – September		July – September		Whole year
	2018	2017	2018	2017	2017
Gross margin non-Durable goods, %	77	79	77	78	78
Gross margin, %	73	76	76	78	76
EBITDA, %	16	13	13	13	15
Operating margin, %	6	2	2	1	5
Net margin, %	6	1	0	-1	4
Equity/assets ratio, %	92	94	92	94	94
Income per share, SEK	0,30	0,03	0,00	-0,01	0,25
Shareholders' equity per share, SEK	20,25	19,02	20,25	19,02	19,26
Share price on closing day, SEK	146,60	94,75	146,60	94,75	94,00

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
	2018	2017	2018	2017	2017
Income after financial items	10 176	1 950	-65	102	7 452
Adjustment for items not affecting cash flow	13 051	9 516	3 576	3 319	13 183
Paid taxes	69	-4 417	-582	-1 255	-2 657
Change in inventories	-2 413	-1 125	-6 954	-399	822
Change in trade receivables	635	7 692	4 342	3 121	-1 013
Change in trade payables	4 482	686	3 416	2 710	4 404
<b>Cash flow from operating activities</b>	<b>26 000</b>	<b>14 302</b>	<b>3 733</b>	<b>7 598</b>	<b>22 191</b>
Cash flow from investing activities	-41 288	-22 006	-11 263	-9 339	-35 523
Cash flow from financing activities	19 204	184 765	-79	-58	184 798
<b>Cash flow for the period</b>	<b>3 916</b>	<b>177 061</b>	<b>-7 609</b>	<b>-1 799</b>	<b>171 466</b>
Liquid funds at beginning of period	195 322	24 871	209 038	203 040	24 871
Exchange rate difference in liquid funds	2 010	-1 114	-181	-423	-1 015
<b>Liquid funds at end of period</b>	<b>201 248</b>	<b>200 818</b>	<b>201 248</b>	<b>200 818</b>	<b>195 322</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, 2017</b>	<b>604</b>	<b>280 890</b>	<b>13 341</b>	<b>21 641</b>	<b>0</b>	<b>316 476</b>
Total comprehensive income Jan - Sep, 2017			-5 205	694		-4 511
Share warrant program		347				347
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	<b>66</b>	<b>186 391</b>				<b>186 457</b>
Acquisition from non-controlling interest				-518		-518
<b>Shareholders' equity as of 30 September, 2017</b>	<b>670</b>	<b>467 628</b>	<b>8 136</b>	<b>21 817</b>	<b>0</b>	<b>498 251</b>
Total comprehensive income Oct - Dec, 2017			482	5 566		6 048
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax		33				33
<b>Shareholders' equity as of 31 december, 2017</b>	<b>670</b>	<b>467 628</b>	<b>8 136</b>	<b>21 817</b>	<b>0</b>	<b>498 251</b>
Retrospective adjustment*				-146		-146
<b>Adjusted Shareholders Equity as of 31 december 2017</b>	<b>670</b>	<b>467 661</b>	<b>8 618</b>	<b>27 237</b>	<b>0</b>	<b>504 186</b>
Total comprehensive income Jan - Sep, 2018			3 440	7 800		11 240
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	5	19 017				19 022
Share warrant program		182				182
<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>0</b>	<b>534 630</b>

\*Effect of the introduction of IFRS 15 "Revenue from contracts with costumers"

## CONDENSED CONSOLIDATED STATEMENT OF NET INCOME PER QUARTER

SEK THOUSANDS	Jul - Sep 2018	Apr - Jun 2018	Jan - Mar 2018	Oct - Dec 2017	Jul - Sep 2017	Apr - Jun 2016	Jan - Mar 2016	Oct - Dec 2016
Net sales	40 914	46 090	42 475	41 568	32 263	37 034	37 477	38 418
Cost of goods sold	-9 876	-13 061	-12 363	-9 731	-7 004	-7 823	-10 388	-9 530
<b>Gross income</b>	<b>31 038</b>	<b>33 029</b>	<b>30 112</b>	<b>31 837</b>	<b>25 259</b>	<b>29 211</b>	<b>27 089</b>	<b>28 888</b>
Selling expenses	-11 846	-11 549	-10 387	-10 819	-10 384	-11 128	-11 371	-10 312
Administrative expenses	-5 513	-4 684	-4 514	-5 391	-4 662	-4 935	-5 057	-6 751
Research and development costs	-11 734	-12 100	-11 537	-10 121	-8 883	-10 537	-9 928	-11 028
Other operating revenues and expenses	-1 207	-697	-525	-767	-941	-646	-720	-771
<b>Operating income</b>	<b>738</b>	<b>3 999</b>	<b>3 149</b>	<b>4 739</b>	<b>389</b>	<b>1 965</b>	<b>13</b>	<b>26</b>
Financial income and expenses	-803	1 315	1 778	763	-287	-79	-51	-131
<b>Income after financial items</b>	<b>-65</b>	<b>5 314</b>	<b>4 927</b>	<b>5 502</b>	<b>102</b>	<b>1 886</b>	<b>-38</b>	<b>-105</b>
Taxes	164	-1 420	-1 120	64	-453	-796	-7	-475
<b>Net income</b>	<b>99</b>	<b>3 894</b>	<b>3 807</b>	<b>5 566</b>	<b>-351</b>	<b>1 090</b>	<b>-45</b>	<b>-580</b>
<b>Attributable to</b>								
Parent Company's shareholders	99	3 894	3 807	5 566	-351	1 090	-45	-580
Non-controlling interests	-	-	-	-	-	-	-	-
	<b>99</b>	<b>3 894</b>	<b>3 807</b>	<b>5 566</b>	<b>-351</b>	<b>1 090</b>	<b>-45</b>	<b>-580</b>
Earnings per share, SEK	0,00	0,15	0,15	0,21	-0,01	0,04	0,00	-0,02
Earnings per share, SEK*	0,00	0,15	0,15	0,21	-0,01	0,04	0,00	-0,02
Average number of outstanding shares	26 402 496	26 378 940	26 190 496	26 190 496	26 190 496	25 765 673	23 614 088	23 614 088
Average number of outstanding shares*	26 786 496	26 378 940	26 190 496	26 402 496	26 402 496	26 140 117	23 829 089	23 829 089
Number of shares at closing day	26 402 496	26 402 496	26 190 496	26 190 496	26 190 496	26 190 496	23 614 088	23 614 088
Number of shares at closing day*	26 879 496	26 402 496	26 190 496	26 402 496	26 402 496	26 402 496	23 829 089	23 829 089
<b>EBITDA</b>	<b>5 207</b>	<b>8 075</b>	<b>7 156</b>	<b>8 585</b>	<b>4 077</b>	<b>5 685</b>	<b>3 676</b>	<b>3 586</b>
Depreciation and amortization of intangible assets	-2 736	-2 699	-2 701	-2 639	-2 631	-2 626	-2 646	-2 618
Depreciation and amortization of fixed assets	-1 733	-1 377	-1 306	-1 207	-1 057	-1 094	-1 017	-942
<b>Operating income</b>	<b>738</b>	<b>3 999</b>	<b>3 149</b>	<b>4 739</b>	<b>389</b>	<b>1 965</b>	<b>13</b>	<b>26</b>

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

## CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME PER QUARTER

SEK THOUSANDS	Jul - Sep 2018	Apr - Jun 2018	Jan - Mar 2018	Oct - Dec 2017	Jul - Sep 2017	Apr - Jun 2016	Jan - Mar 2016	Oct - Dec 2016
<b>Net income</b>	<b>99</b>	<b>3 894</b>	<b>3 807</b>	<b>5 566</b>	<b>-351</b>	<b>1 090</b>	<b>-45</b>	<b>-580</b>
<b>Other comprehensive income</b>								
<i>Items that may be reclassified to the income statement</i>								
Exchange rate differences	-801	4 413	137	509	-2 276	-2 686	-735	2 586
Tax attributable to items that have been transferred, or can be transferred to net income	81	-466	76	-27	210	245	36	-230
<b>Total other comprehensive income, net after tax</b>	<b>-720</b>	<b>3 947</b>	<b>213</b>	<b>482</b>	<b>-2 066</b>	<b>-2 441</b>	<b>-699</b>	<b>2 356</b>
<b>Total comprehensive income</b>	<b>-621</b>	<b>7 841</b>	<b>4 020</b>	<b>6 048</b>	<b>-2 417</b>	<b>-1 351</b>	<b>-744</b>	<b>1 776</b>
<b>Attributable to</b>								
Parent Company's shareholders	-621	7 841	4 020	6 048	-2 417	-1 351	-744	1 776
Non-controlling interests	-	-	-	-	-	-	-	-
	<b>-621</b>	<b>7 841</b>	<b>4 020</b>	<b>6 048</b>	<b>-2 417</b>	<b>-1 351</b>	<b>-744</b>	<b>1 776</b>



## CONDENSED INCOME STATEMENT FOR THE PARENT COMPANY

SEK THOUSANDS	January – September		July – September		Whole year
	2018	2017	2018	2017	2017
Net sales	111 335	87 685	41 432	31 982	123 345
Cost of goods sold	-28 794	-21 216	-10 203	-6 817	-28 462
<b>Gross income</b>	<b>82 541</b>	<b>66 469</b>	<b>31 229</b>	<b>25 164</b>	<b>94 883</b>
Selling expenses	-19 545	-18 826	-6 461	-5 172	-27 175
Administrative expenses	-7 578	-8 380	-3 407	-2 082	-9 736
Research and development costs	-33 812	-29 348	-12 657	-8 899	-38 955
Other operating revenues and expenses	-1 939	-2 844	-832	-1 164	-3 899
<b>Operating income</b>	<b>19 667</b>	<b>7 071</b>	<b>7 872</b>	<b>7 847</b>	<b>15 118</b>
Financial income and expenses	4 284	-2 064	-900	-1 058	-890
<b>Income after financial items</b>	<b>23 951</b>	<b>5 007</b>	<b>6 972</b>	<b>6 789</b>	<b>14 228</b>
Year end dispositions	-	-	-	-	-3 900
Taxes	-5 441	-1 102	-1 575	-1 494	-2 486
<b>Net income</b>	<b>18 510</b>	<b>3 905</b>	<b>5 397</b>	<b>5 295</b>	<b>7 842</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 10 586 thousand (9 923), of which SEK 3 680TSEK (3 895) for the quarter.

## CONDENSED BALANCE SHEET FOR THE PARENT COMPANY

SEK THOUSANDS	Sept 30, 2018	Sept 30, 2017	Dec 31, 2017
<b>ASSETS</b>			
Intangible fixed assets	139 416	105 057	111 697
Property, plant and equipment	7 962	9 889	10 713
Financial assets	200 627	196 564	203 474
<b>Total non-current assets</b>	<b>348 005</b>	<b>311 510</b>	<b>325 884</b>
Inventories	12 085	6 959	7 304
Current receivables	20 493	16 785	23 422
Cash and bank	190 294	184 662	173 421
<b>Total current assets</b>	<b>222 872</b>	<b>208 406</b>	<b>204 147</b>
<b>Total assets</b>	<b>570 877</b>	<b>519 916</b>	<b>530 031</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
Shareholders' equity	529 959	488 247	492 245
Untaxed reserves	8 913	8 213	8 913
Provisions	1 334	7 114	1 351
Short-term non-interest-bearing liabilities	30 671	16 342	27 522
<b>Total shareholders' equity and liabilities</b>	<b>570 877</b>	<b>519 916</b>	<b>530 031</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 2018 the Group has started to apply IFRS 9 *Financial instruments* and IFRS 15 *Revenue from contracts with customers*. The effects of the transition is presented below.

### IFRS 9 Financial instruments

IFRS 9 *Financial instruments* has replaced IAS 39: *Financial Instruments: Recognition and Measurement* from January 1, 2018. The change of accounting principle has not had a significant effect on the groups' result and financial position. According to IFRS 9 a new impairment model, the "expected credit loss model", replaces the model used in prior periods – the "incurred loss model". The new model has been implemented during 2018 without a need for extra impairment of the assets of the Group.

### IFRS 15 Revenue from contracts with customers

As per 1 January, 2018, IFRS 15 *Revenue from contracts with customers* has replaced earlier existing accounting standards such as IAS 18 *Revenue*, IAS 11 *Construction contracts* and IFRIC 13 *Customer loyalty programs*.

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 there may be several distinct performance obligations in one and the same contract. IFRS 15 means that revenue related to some of these obligations (such as installation of capital goods and education and learning) will be postponed in comparison with earlier accounting principles.

The group present figures in the financial statements of 2018 that have been affected by the application of IFRS 15. Opening balances in equity have decreased with 146 KSEK (net tax) due to the postponement of revenue of 188 KSEK. This revenue was related to performance obligations in a customer contract that was entered during 2017. The revenue was recognized during the first quarter of 2018 in connection with the fulfillment of the obligations. At period end it did not exist any ongoing customer contracts with outstanding performance obligations.

According to IFRS 15, companies must disclose how the affected figures would have been presented if IFRS 15 was not applied. With the old accounting principles, sales for the current year would have been 188 KSEK lower and tax expense 41 KSEK lower; offset by the fact that the equity opening balance would have been 146 KSEK higher.

### IFRS 16 Leases

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 will apply IFRS 16 as per January 1, 2019. As an operational lessee, the company will be impacted by the introduction of IFRS 16. Primarily because lease contracts for offices and warehouses will be accounted as financial leases and not as operational leases. 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 will be affected of the new accounting standard.

## Note 2. Share warrant programs

In total there are 477.000 outstanding warrants in two programs. The Annual General Meeting of 2017 resolved to issue no more than 243.000 warrants (series 2017/2019), with the right to subscribe a maximum of 243.000 new shares to employees of the XVIVO Perfusion Group. As per September 30, 2018, 198.000 of these warrants have been subscribed for and paid. The Annual General Meeting 2018 decided to issue no more than 315.000 warrants (series 2018/2020), with the right to subscribe for no more than 315.000 new shares to employees in XVIVO Perfusion Group. As per September 30, 2018, 279.000 were subscribed for and paid.

As per September 30, the closing share price exceeded the strike price for both warrant programs. This results in a dilution effect on existing shares. If all warrants are exercised for subscription of shares, the share capital will increase by approximately SEK 12.000 and the number of shares will increase by a total of 477.000, corresponding to a dilution of approximately 1.8 percent of the total number of shares and votes.

Warranty Program 2017/2019 consists of 198.000 warrants and each warrant entitle the holder to subscribe for a new share at a price of SEK 138.51 in May 2019. Warranty Program 2018/2020 consists of 279.000 warrants and each warrant in May 2020 entitles the holder to subscribe for a new share at a price of SEK 146.02.

## Note 3. Financial data per segment, group

SEK THOUSANDS	January – September					
	Net sales of non-Durable goods		Durable goods		Total consolidated	
	2018	2017	2018	2017	2018	2017
Net sales	120 360	101 552	9 119	5 222	129 479	106 774
Cost of goods sold	-27 885	-21 496	-7 415	-3 719	-35 300	-25 215
<b>Gross income</b>	<b>92 475</b>	<b>80 056</b>	<b>1 704</b>	<b>1 503</b>	<b>94 179</b>	<b>81 559</b>

SEK THOUSANDS	July – September					
	Net sales of non-Durable goods		Durable goods		Total consolidated	
	2018	2017	2018	2017	2018	2017
Net sales	40 251	31 573	663	689	40 914	32 262
Cost of goods sold	-9 413	-7 004	-463	1	-9 876	-7 003
<b>Gross income</b>	<b>30 838</b>	<b>24 569</b>	<b>200</b>	<b>690</b>	<b>31 038</b>	<b>25 259</b>

## Note 4. Financial instruments

The Group's financial assets and liabilities valued at acquisition value amount to SEK 237 (228) million and SEK 40 (24) 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
	2018	2017	2018	2017	2017
<b>Operating income</b>	<b>7 886</b>	<b>2 367</b>	<b>738</b>	<b>389</b>	<b>7 106</b>
Depreciation and amortization of intangible assets	8 136	7 903	2 736	2 631	10 542
Depreciation and amortization of fixed assets	4 416	3 168	1 733	1 057	4 375
<b>EBITDA</b>	<b>20 438</b>	<b>13 438</b>	<b>5 207</b>	<b>4 077</b>	<b>22 023</b>

## Gross margin

SEK THOUSANDS	Jan – Sep		Jul – Sep		Whole year
	2018	2017	2018	2017	2017
<i>Operating income</i>					
Net sales	129 479	106 774	40 914	32 263	148 342
<i>Operating expenses</i>					
Cost of goods sold	-35 300	-25 215	-9 876	-7 004	-34 946
<b>Gross income</b>	<b>94 179</b>	<b>81 559</b>	<b>31 038</b>	<b>25 259</b>	<b>113 396</b>
<b>Gross margin %</b>	<b>73</b>	<b>76</b>	<b>76</b>	<b>78</b>	<b>76</b>

## Gross margin non-durable goods

SEK THOUSANDS	Jan – Sep		Jul – Sep		Whole year
	2018	2017	2018	2017	2017
<i>Operating income</i>					
Net sales of non-durable goods	120 360	101 552	40 251	31 573	140 994
<i>Operating expenses</i>					
Cost of non-durable goods sold	-27 885	-21 496	-9 413	-7 004	-30 362
<b>Gross income, non-durable goods</b>	<b>92 475</b>	<b>80 056</b>	<b>30 838</b>	<b>24 569</b>	<b>110 632</b>
<b>Gross margin, non-durable goods %</b>	<b>77</b>	<b>79</b>	<b>77</b>	<b>78</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	Sep 30, 2018	Sep 30, 2017	Dec 31, 2017
Shareholders' equity	534 630	498 188	504 332
Total assets	578 746	528 372	538 540
<b>Equity/assets ratio %</b>	<b>92</b>	<b>94</b>	<b>94</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 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



XPST™, Durable goods



XPS Disposable Kit™

## WARM PERFUSION



LS™, Durable goods



LS Disposable Kit™

## ACCESSORIES



STEEN Solution™



XVIVO Organ Chamber™



XVIVO Lung Cannula Set™

## COLD PERFUSION



PERFADEX®



PERFADEX® PLUS



Silicone Tubing Set™





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