

# REPORT ON OPERATIONS 2016

## 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.*



# CONTINUED SALES GROWTH, POSITIVE EBITDA, AND STRENGTHEN DEVELOPMENT PORTFOLIO

## THE PERIOD 2016 (JAN – DEC)

- Net sales in the period amounted to SEK 138.2 (120.2) million, corresponding to an increase of 15 percent. Growth amounted to 13 percent in local currency. The acquisition of Vivoline had a positive impact of SEK 4.3 million on sales.
- Operating income before depreciation and amortization (EBITDA,) excluding items affecting comparability, increased by 27 percent and amounted to SEK 26.4 (20.8) million, corresponding to an EBITDA margin of 19 percent. Items affecting comparability of SEK 10.4 (2.0) million, related to the Nasdaq Stockholm main market listing and the acquisition of Vivoline, have been charged against the period. EBITDA amounted to SEK 16.0 (18.8) million, corresponding to an EBITDA margin of 12 percent.
- Operating income amounted to SEK 2.7 (7.2) million, after amortization and depreciation of SEK 13.2 (11.6) million was charged against the period.
- Net income amounted to SEK 1.5 (5.1) million, resulting in earnings per share of SEK 0.07 (0.24).
- Cash flow from operating activities was SEK 12.6 (8.6) million.
- Total sales from warm perfusion (STEEN Solution™, XPS™, LS™, and products and services related to the use of the XPS™ and LS™) accounted for 40 (39) percent of the total sales.
- During the period, ten XPS™ and LS™ were sold; four to Europe, and six to the US. France, Spain, and Switzerland were new countries that received access to the XPS™ or LS™ during the period.
- XVIVO Perfusion's patent-protected product, PrimECC®, has been granted a CE-mark. The product, developed to prime the heart-lung machine before open heart surgery, is undergoing a clinical study.
- STEEN Solution™ was used for the first time to give localized delivery of a chemotherapy agent to a patient suffering from metastatic lung sarcoma through In-Vivo Lung Perfusion (IVLP).

## FOURTH QUARTER 2016 (OCT - DEC)

- Net sales in the quarter amounted to SEK 38.4 (32.7) million, corresponding to an increase of 18 percent. Growth amounted to 11 percent in local currency. The acquisition of Vivoline had a positive impact of SEK 2.8 million on sales.
- Operating income before depreciation and amortization (EBITDA), excluding items affecting comparability, amounted to SEK 6.7 (7.2) million, corresponding to an EBITDA margin of 17 percent. Items affecting comparability of SEK 3.1 (0.3) million, related to the Nasdaq Stockholm main market listing and the acquisition of Vivoline, have been charged against the quarter. EBITDA amounted to SEK 3.6 (6.9) million, corresponding to an EBITDA margin of 9 percent.
- Operating income amounted to SEK 0.0 (3.8) million, after amortization and depreciation of SEK 3.6 (3.1) million was charged against the quarter.
- Net income amounted to SEK -0.6 (2.8) million, resulting in earnings per share of SEK -0.02 (0.13).
- Cash flow from operating activities was SEK -6.2 (2.9) million, mainly affected by change in trade receivables of SEK -11.8 million from increased sales and prepaid insurance premiums.
- Total sales from warm perfusion (STEEN Solution™, XPS™, LS™\*, and products and services related to the use of the XPS™ and LS™) accounted for 43 (40) percent of the total sales.
- Four XPS™ and LS™ were delivered during the quarter; two XPS™ went to the USA, and two LS™ went to Spain. The LS™ machine is new to Spain.
- During the quarter, XVIVO Perfusion acquired another 1.4 percent of the shares in the listed company Vivoline Medical AB, through the compulsory redemption process, whereby XVIVO Perfusion became the owner of 100 percent of the shares.
- XVIVO Perfusion AB's shares were admitted for trading on Nasdaq Stockholm main list on November 28, 2016. The company's shares will continue trading with the same short name and ISIN code.
- An XPS™ contract has been signed with Alfred Health, Melbourne, Australia. It is the first XPS™ to be sold to the country. Delivery and installation are planned for Q1, 2017.

## SIGNIFICANT EVENTS AFTER THE END OF THE QUARTER

- An XPS™ contract has been signed with Alfred Health, Melbourne, Australia. It is the first XPS™ to be sold to the country. Delivery and installation are planned for Q1, 2017.

## MILESTONES PASSED DURING THE YEAR

Acquisition of Vivoline. Integration and strengthening of organization completed.

First clinical study on STEEN Solution™ In-Vivo Lung Perfusion for cancer patients initiated.

Renewed collaboration with Stig Steen's research institute, focusing on heart and lung transplant research to strengthen XVIVO Perfusion's research portfolio.

First results from first liver transplant study using STEEN Solution™ published with good clinical results.

PrimECC® CE-marked and clinical study on PrimECC® initiated.

XVIVO Perfusion AB's share included for trade in Nasdaq Stockholm's main index (Midcap).

## CONFERENCE CALL

CEO Magnus Nilsson will present the report in a conference call at 2 p.m. CET on Wednesday, February 8, 2017.  
Telephone: +44 (0) 2071 928 000, enter code 13300522

## CEO'S COMMENTS



2016 was yet another successful and eventful year for XVIVO Perfusion, wherein several important milestones were reached. The most important of these was the acquisition of Vivoline, thereby strengthening the company in the field of lung transplantation, and adding an interesting and well-

developed heart transplantation project to the company's portfolio. The acquisition also means greater sales potential in Europe, where the number of installed perfusion machines immediately increased from six to sixteen. The acquisition of Vivoline also entailed increased resources within training and other customer services. Other important milestones were that two of the research projects within new indications advanced to the clinical phase – PrimECC®, which is a priming solution for heart-lung machines, and STEEN Solution™, In-Vivo Lung Perfusion for cancer patients. As a result of this, the company has products in clinical studies within four indications at the turn of the year. Finally, an important event for the company was that its shares began trading on Nasdaq Stockholm's main list (Midcap), which means that more players can invest in XVIVO Perfusion's shares.

We are also pleased that sales growth continued to be strong (+15 percent) during the year. It is important to note that this sales performance has been accompanied by a continued good gross margin and an improved EBITDA margin adjusted for items affecting comparability, despite the fact that large investments were made in research, and the marketing organization was built up during the year.

### INTEGRATION OF VIVOLINE

Integration has been quicker than anticipated, and integration of administration, sales, and research was completed as early as the quarter following the acquisition. After the merger, focus has been entirely on building up resources to be able to accelerate the heart project. In late autumn 2017, some contract manufacturing will be transferred to XVIVO's upgraded clean room facilities in Lund. This will be done in order to increase efficiency and reduce production costs.

### INCREASED FOCUS ON RESEARCH WITHIN NEW INDICATIONS

The acquisition has meant renewed developmental collaboration with Professor Steen's research institute, especially within the advanced and well-developed heart transplant project, and a new development organization with premises in Lund,

which were built up during the latter part of 2016. Through this significant strengthening of both product development resources and projects in a late phase, together with the rapid development of the company's other research projects, XVIVO greatly increased its commercial potential during 2016. If the projects continue to be successful, this potential will be gradually realized as early as within two to four years. To take advantage of this greater commercial potential, the company will focus more resources on taking these development projects to the market.

Regarding the latest project close to entering the clinical development phase, perfusion/preservation of the heart before transplantation, a prototype is ready which is intended to be used in the first clinical study, planned to start as soon as all regulatory approval has been obtained. In parallel with the heart project, clinical phase research is ongoing to extend the use of warm perfusion using STEEN Solution™ for the liver and drug administration to isolated organs. This is part of the long-term work with the goal of becoming the global leader in the field of organ perfusion. Apart from this, XVIVO is developing innovative solutions for use within thorax surgery, i.e. for the same target group of doctors as within lung and heart transplantation.

### OUTLOOK FOR 2017: FOCUS ON GLOBAL LEADERSHIP IN THE FIELD OF ORGAN PERFUSION

A strong focus of our business is to establish the XPS™ and STEEN Solution™ globally as standard treatment for organ transplantation. To this end, the company aims to continue to expand the installation base of the XPS™ and LS™ in the world and, in parallel, to increase the resources regarding training and service for the transplantation clinics so as to support them and increase the percentage of transplantations of the donated organs. The focus of XVIVO's research is to continue to lead the development of innovative solutions within thorax surgery, to develop and extend the use of perfusion of more organs for transplantation, and to treat isolated organs and tissue, one example of which is the indication of cancer.

Magnus Nilsson  
CEO

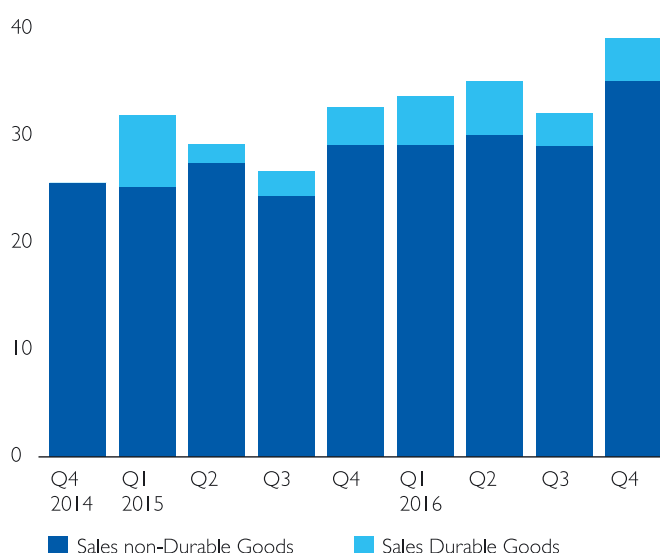


## FOURTH QUARTER 2016 (OCTOBER - DECEMBER)

### NET SALES

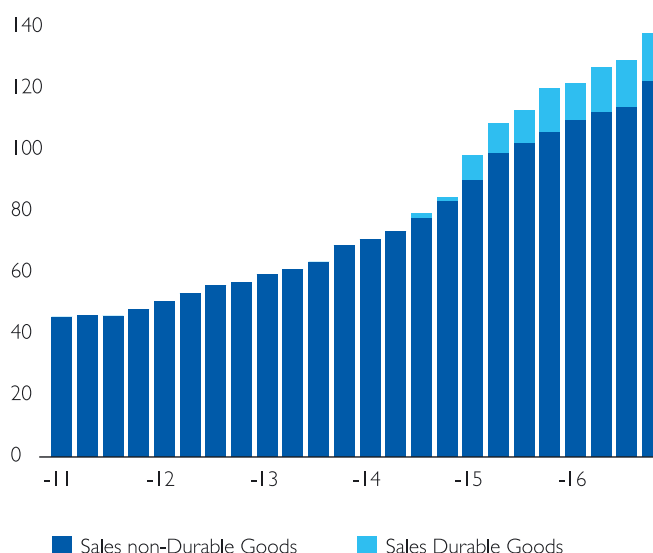
XVIVO Perfusion's net sales of non-Durable goods\* in the quarter amounted to SEK 34.6 (29.1) million, corresponding to an increase of 19 percent in SEK and 11 percent in local

NET SALES PER QUARTER (SEK MILLIONS)\*



currency. The acquisition of Vivoline had a positive impact of SEK 1.7 million on sales of non-Durable goods. Total net sales in the quarter amounted to SEK 38.2 (32.7) million, corresponding to an increase of 18 percent in SEK and 11 percent in local currency. The acquisition of Vivoline had a positive impact of SEK 2.8 million on total sales during the quarter. Integration of Vivoline's organization completed during the quarter and the LS™ and DLS™ have been marketed by XVIVO's sales force during the quarter.

NET SALES ROLLING 12 MONTHS (SEK MILLIONS)\*



## COMPILATION OF NET SALES AND EBITDA

SEK THOUSANDS	January - December 2015		October - December 2016	
Net Sales non-Durable Goods	122 527	105 977	34 552	29 139
Net Sales Durable Goods	15 650	14 268	3 866	3 541
<b>Net Sales Total</b>	<b>138 177</b>	<b>120 245</b>	<b>38 418</b>	<b>32 680</b>
Cost of Goods non-Durable Goods	-24 798	-23 826	-6 936	-5 877
Cost of Goods Durable goods	-11 144	-11 459	-2 594	-2 178
Cost of Goods Total	-35 942	-35 285	-9 530	-8 055
Gross income non-Durable Goods	97 729	82 151	27 616	23 262
Gross margin non-Durable Goods, %	80%	78%	80%	80%
Gross income Durable Goods	4 506	2 809	1 272	1 363
Gross income Total	102 235	84 960	28 888	24 625
Gross margin Total, %	74%	71%	75%	75%
Selling expenses	-35 708	-32 052	-10 312	-9 095
Administrative expenses	-24 489	-13 154	-6 751	-3 384
Research and development costs	-36 670	-31 086	-11 028	-7 878
Other operating revenues and expenses	-2 634	-1 456	-771	-475
<b>Operating Income</b>	<b>2 734</b>	<b>7 212</b>	<b>26</b>	<b>3 793</b>
amortization and depreciation cost of goods sold	-297	-	-115	-
depreciation administrative expenses	-484	-516	-152	-240
amortization of research and development expenses	-10 346	-10 155	-2 618	-2 506
depreciation other operative expenses	-2 091	-918	-675	-343
<b>EBITDA</b>	<b>15 952</b>	<b>18 801</b>	<b>3 586</b>	<b>6 882</b>
EBITDA, %	12%	16%	9%	21%
Items affecting comparability	-10 399	-1 963	-3 087	-311
EBITDA excluding items affecting comparability	26 351	20 764	6 673	7 193
EBITDA excluding items affecting comparability, %	19%	17%	17%	22%

Warm perfusion sales from non-durable goods (STEEN Solution™, products and services related to the use of the XPS™ and LS™) accounted for 36 (32) 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 43 (40) percent of the total sales.

## INCOME

Operating income before depreciation and amortization (EBITDA), excluding items affecting comparability, amounted to SEK 6.7 (7.2) million, corresponding to an EBITDA margin of 17 percent. The main reason for the decrease is that SEK 1.6 million were charged against the quarter, attributable to a bonus program in the American subsidiary where the accrual is based on the share price. Items affecting comparability of SEK 3.1 (0.3) million have been charged against the quarter; whereof SEK 1.2 million are related to the Nasdaq application, SEK 1.2 million are transaction costs related to the Vivoline acquisition, and SEK 0.7 million are integration costs related to the integration of Vivoline. EBITDA amounted to SEK 3.6 (6.9) million, corresponding to an EBITDA margin of 9 percent.

Operating income amounted to SEK 0.0 (3.8) million, after amortization and depreciation of SEK 3.6 (3.1) million was charged against the quarter.

The gross margin for non-Durable goods during the quarter was 80 (80) percent. The total gross margin during the quarter was 75 (75) percent.

Selling expenses in relation to sales decreased during the quarter to 27 (28) percent, mainly due to economies of scale. R&D expenses amounted to 29 (24) percent of sales. The increase is mainly attributable to the implementation of a new quality system amounting to SEK 0.7 million charged against the quarter, and increased costs of research into new indications. Costs related to the company's application to Nasdaq Stockholm's main list and bid for Vivoline totaling SEK 2.6 million have been charged against the quarter; which is the main reason that the administrative expenses rose to 18 percent (10) of sales. Without these costs, administrative expenses were 11 (9) percent of sales. This increase is mainly due to higher 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 -0.8 (-0.5) million.

During the quarter, SEK 5.2 (1.6) million of the development costs were capitalized as an intangible asset. SEK 2.1 (1.6) million was attributable to the continued NOVEL study with STEEN Solution™ with the aim of PMA approval, SEK 1.5 million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, and SEK 1.6 million was attributable to product development of the product portfolio. Depreciation and amortization for

the period amounted to SEK 3.6 (3.1) 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 -6.2 (2.9) million, mainly affected by change in trade receivables of SEK -11.8 million from increased sales and prepaid insurance premiums. Investments amounted to SEK 9.4 (4.2) million, of which SEK 5.5 (1.6) million was invested in intangible assets and SEK 2.2 (1.5) million was invested in tangible assets. Investments in tangible assets consisted primarily of one XPS. The cash flow effect of the Vivoline acquisition was SEK 1.7 million and was charged against investments. The cash flow from financing activities was SEK 0.0 (0.0) million. Cash and cash equivalents at the end of the quarter amounted to SEK 24.9 (41.2) million.

## ACQUISITION OF VIVOLINE

During the quarter, XVIVO Perfusion acquired another 1.4 percent of the shares in the listed company Vivoline Medical AB, whereby XVIVO Perfusion became the owner of 100 percent of the shares and 99.6 percent of the warrants. Vivoline's shares and warrants were delisted from Nasdaq First North on July 8, 2016. Acquisition expenses attributable to the acquisition amounted to SEK 4.5 million and have been charged to "Administrative expenses" in the consolidated income statement during the year. Transaction costs that are directly attributable to the new issue of shares have been charged against equity and amount to SEK 0.6 million net after tax.

Vivoline Medical AB operates in the field of lung transplantation and has research collaboration with Professor Stig Steen and Igelösa in the field of heart transplantation. The combined company creates more resources and competence to take Professor Stig Steen's world-leading research in the field of heart transplantation to a commercial phase. Furthermore, when market approval has been obtained, there will be opportunities for a rapid introduction onto the market, thanks to XVIVO Perfusion's existing well-developed global sales and marketing organization. The acquisition also strengthens XVIVO Perfusion's market position in the field of lung transplantation in Europe and Australia, and enables synergies in cleanroom production, product development, regulatory issues, and marketing. The acquisition is in line with XVIVO Perfusion's strategic objective of becoming the leader in thoracic transplantation.

## XVIVO PERFUSION AB ADMITTED TO TRADING ON NASDAQ STOCKHOLM MAIN LIST

XVIVO Perfusion applied for listing of XVIVO Perfusion's shares on the Nasdaq Stockholm's main list. Nasdaq approved the Company's application and the first day of trading in XVIVO Perfusion's shares on Nasdaq Stockholm was 28 November 2016. The company's shares will continue trading with the same short name and ISIN code.

# THE PERIOD 2016 (JANUARY – DECEMBER)

## NET SALES

XVIVO Perfusion's net sales of non-Durable goods\* in the period amounted to SEK 122.5 (106.0) million, corresponding to an increase of 16 percent in SEK and 14 percent in local currency. The acquisition of Vivoline had a positive impact of SEK 3.2 million on sales of non-Durable goods. Total net sales in the period amounted to SEK 138.2 (120.2) million, corresponding to an increase of 15 percent in SEK and 13 percent in local currency. The acquisition of Vivoline had a positive impact of SEK 4.3 million on 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 32 (30) 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 40 (39) percent of the total sales.

## INCOME

Operating income before depreciation and amortization (EBITDA), excluding items affecting comparability, increased by 27 percent and amounted to SEK 26.4 (20.8) million, corresponding to an EBITDA margin of 19 percent. Items affecting comparability of SEK 10.4 (2.0) million have been charged against the period, whereof SEK 2.9 million are related to the Nasdaq application, SEK 4.5 million are transaction costs related to the Vivoline acquisition and SEK 3.0 million are integration costs related to the integration of Vivoline. EBITDA amounted to SEK 16.0 (18.8) million, corresponding to an EBITDA margin of 12 percent.

Operating income amounted to SEK 2.7 (7.2) million, after amortization and depreciation of SEK 13.2 (11.6) million was charged against the period.

The gross margin for non-Durable goods during the period was 80 (78) percent; the increase is mainly attributable to improved price position on strategic products and economies of scale. The total gross margin during the period was 74 (71) percent; the change is mainly attributable to improved product mix and economies of scale.

Selling expenses in relation to sales decreased during the period to 26 (27) percent, mainly due to economies of scale. Integration costs related to the integration of Vivoline amounting to SEK 2.0 million were charged against selling expenses during the period. Excluding these costs, selling expenses in relation to sales were 24 (27) percent. R&D expenses amounted to SEK 27 (26) percent of sales. The increase is mainly attributable to the implementation of a new quality system, and increased costs of research into new indications. Costs related to the company's application to Nasdaq

Stockholm's main list and bid for Vivoline totaling SEK 8.3 million have been charged against administration expenses during the period, which is the main reason that the administrative expenses rose to 18 percent (11) of sales. Without these costs, administrative expenses were 12 (11) percent of sales. This increase is mainly due to double costs for XVIVO Perfusion's and Vivoline's administration in the third quarter, and one additional employee compared to the same period last year. Net other operating revenues and expenses during the period were SEK -2.6 (-1.5) million.

During the period, SEK 10.9 (5.8) million of the development costs were capitalized as an intangible asset. SEK 6.3 million was attributable to the continued NOVEL study with STEEN Solution™ with the aim of PMA approval, SEK 2.4 million was attributable to investments in the heart transplant project with aim of marketing approval in the USA and Europe, and SEK 2.2 million was attributable to product development of the product portfolio. Depreciation and amortization for the period amounted to SEK 13.2 (11.6) million, of which SEK 9.8 (9.8) million was amortization of the FDA HDE approval.

## CASH FLOW

Cash flow from operating activities amounted to SEK 12.6 (8.6) million. Investments amounted to SEK 29.8 (14.3) million, of which SEK 11.9 (6.1) million was invested in intangible assets and SEK 8.6 (7.1) million was invested in tangible assets. Investments in tangible assets consisted primarily of four XPS™, including one for training, in Europe. The cash flow effect of the Vivoline acquisition was SEK 9.5 million and was charged against investments. The cash flow from financing activities was SEK 0.2 (-1.5) million. Cash and cash equivalents at the end of the period amounted to SEK 24.9 (41.2) million.

## FINANCING

XVIVO Perfusion's total credit facilities consist of an overdraft facility that at the end of the period amounted to SEK 22 (20) million, of which SEK 0.0 (0.0) million was utilized. The equity/assets ratio was 91 (91) percent at the end of the period.

## FIRST PATIENT IN PRIMECC® STUDY INCLUDED

PrimECC® is a CE-marked and patent-protected product, developed to prime the heart-lung machine before open heart surgery. The study that has now started is intended to expand the clinical documentation for PrimECC® and will include a total of 80 patients. Several hundred thousand heart operations are performed in the world each year using a heart-lung machine, and the 'proof of concept' study earlier 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. The company does not plan any extensive launch of the product before this study is complete. XVIVO Perfusion has applied for a patent for PrimECC® in important markets and has so far been granted a patent in the USA and the EU.

## **LUNG CANCER PATIENT GIVEN CHEMOTHERAPY THROUGH IN-VIVO LUNG PERFUSION WITH STEEN SOLUTION™**

STEEN Solution™ was used for the first time to give localized delivery of a chemotherapy agent to a patient suffering from metastatic lung sarcoma through In-Vivo Lung Perfusion (IVLP). This was also the first time STEEN Solution was used to perfuse a lung on In-Vivo, i.e. on a living patient. The aim of the study is to prove safety and evaluate the ability to use STEEN Solution™ to improve isolated tissue therapy. The use of systemic chemotherapy has not been used due to the significant side effects with unproven benefit. With the use of IVLP, the surgeon can shut off the lung from the systemic circulation and give the chemotherapy only to the lung so as not to affect the rest of the body.

## **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 during this year 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 2 million, which will be charged against 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.

### **NEW INDICATIONS**

The company conducts preclinical and clinical research in transplantation of organs other than lungs as well as drug delivery to an isolated organ.

### **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 focuses on getting lung evaluation outside the body using the XPS™ and STEEN Solution™ accepted as a standard procedure. A basic precondition of the strategy is to obtain regulatory approval for STEEN Solution™ in all important markets. XVIVO Perfusion has demonstrated through published preclinical and clinical studies that warm perfusion of organs using the STEEN Solution™ method results in more available organs, thereby giving more patients the potential to have a life-saving treatment, better quality of life, socioeconomic gains, and lower morbidity and mortality. Furthermore, the company will strive to increase awareness of the STEEN Solution™ method in important groups of stakeholders and will work with key opinion leaders in the area.

## **OTHER INFORMATION**

### **ORGANIZATION AND PERSONNEL**

At the end of quarter the number of employees was 28, of whom 13 were women and 15 were men. Of these, 15 people were employed in Sweden and 13 in the USA. In addition, the company uses around five consultants.



## INFORMATION ON TRANSACTIONS WITH RELATED PARTIES

No transactions have been carried out with related parties during the quarter.

## PROPOSED APPROPRIATION OF EARNINGS

It is the intention of the Board to propose to the Annual General Meeting that no dividend should be paid during 2017.

## 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 2015 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.

## ELECTION COMMITTEE

The following people have been appointed as members of XVIVO Perfusion's Election Committee for the 2017 Annual General Meeting:

Gösta Johannesson representing Bure Equity AB  
Martin Lewin representing Eccenovo AB  
Thomas Olausson

The appointments have been made in accordance with the instructions regarding principles for the appointment of the company Election Committee which were determined at the Annual General Meeting of XVIVO Perfusion AB (publ) on May 3, 2016.

## ANNUAL GENERAL MEETING 2017 AND ANNUAL REPORT

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on April 26, 2017 in Gothenburg. Shareholders who wish to have an item considered at the Annual General Meeting can submit a written request to the Board to this effect. Such a request for an item to be considered is to be sent to XVIVO Perfusion AB (publ), Att: Chairman of the Board, Box 53015, 400 14 Gothenburg, and must have been received by the Board no later than seven weeks before the Annual General Meeting, or otherwise in such good time that the matter, where necessary, can be included in the notice to attend the Annual General Meeting.

It is estimated that XVIVO Perfusion's Annual Report for 2016 will be available for download on XVIVO Perfusion's website during the week commencing Monday, April 3.

## 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.

February 8, 2017  
Gothenburg

The Board

## THIS REPORT HAS NOT BEEN REVIEWED BY THE COMPANY'S AUDITORS.

## FINANCIAL REPORTS

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

Following reports are planned to be submitted:  
Interim Report January-March 2017: Tuesday, April 25 2017  
Interim Report January-June 2017: Friday, July 14 2017  
Interim Report January-September 2017: Friday, October 27 2017  
Report on Operations 2017: Friday, February 9, 2018

## 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 February 8, 2017 at 8.30 am.*

# CONSOLIDATED INCOME STATEMENTS

SEK THOUSANDS	January - December 2016		October - December 2015	
Net sales	138 177	120 245	38 418	32 680
Cost of goods sold	-35 942	-35 285	-9 530	-8 055
<b>Gross income</b>	<b>102 235</b>	<b>84 960</b>	<b>28 888</b>	<b>24 625</b>
Selling expenses	-35 708	-32 052	-10 312	-9 095
Administrative expenses	-24 489	-13 154	-6 751	-3 384
Research and development costs	-36 670	-31 086	-11 028	-7 877
Other operating revenues and expenses	-2 634	-1 456	-771	-475
<b>Operating income</b>	<b>2 734</b>	<b>7 212</b>	<b>26</b>	<b>3 794</b>
Financial income and expenses	259	186	-131	-122
<b>Income after financial items</b>	<b>2 993</b>	<b>7 398</b>	<b>-105</b>	<b>3 672</b>
Taxes	-1 492	-2 267	-475	-874
<b>Net income</b>	<b>1 501</b>	<b>5 131</b>	<b>-580</b>	<b>2 798</b>
<b>Attributable to</b>				
Parent Company's shareholders	1 501	5 131	-580	2 798
Non-controlling interests	-	-	-	-
	<b>1 501</b>	<b>5 131</b>	<b>-580</b>	<b>2 798</b>
Earnings per share, SEK	0,07	0,24	-0,02	0,13
Earnings per share, SEK*	0,07	0,24	-0,02	0,13
Average number of outstanding shares	22 567 807	21 512 769	23 614 088	21 512 769
Average number of outstanding shares*	22 782 807	21 561 519	23 829 088	21 512 769
Number of shares at closing day	23 614 088	21 512 769	23 614 088	21 512 769
Number of shares at closing day*	23 829 088	21 512 769	23 829 088	21 512 769
<b>EBITDA</b>	<b>15 952</b>	<b>18 801</b>	<b>3 586</b>	<b>6 881</b>
Amortization	-10 357	-10 155	-2 618	-2 504
Depreciation	-2 861	-1 434	-942	-583
<b>Operating income</b>	<b>2 734</b>	<b>7 212</b>	<b>26</b>	<b>3 794</b>

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

# STATEMENTS OF COMPREHENSIVE INCOME

SEK THOUSANDS	January - December 2016		October - December 2015	
<b>Net income</b>	<b>1 501</b>	<b>5 131</b>	<b>-580</b>	<b>2 798</b>
<b>Other comprehensive income</b>				
<i>Items that may be reclassified to the income statement</i>				
Exchange rate differences	4 658	3 119	2 586	-182
Tax attributable to items that have been transferred, or can be transferred to net income	-457	-328	-230	19
<b>Total other comprehensive income, net after tax</b>	<b>4 201</b>	<b>2 791</b>	<b>2 356</b>	<b>-163</b>
<b>Total comprehensive income</b>	<b>5 702</b>	<b>7 922</b>	<b>1 776</b>	<b>2 635</b>
<b>Attributable to</b>				
Parent Company's shareholders	5 702	7 922	1 776	2 635
Non-controlling interests	-	-	-	-
	<b>5 702</b>	<b>7 922</b>	<b>1 776</b>	<b>2 635</b>

# CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

SEK THOUSANDS	Dec 31, 2016	Dec 31, 2015
<b>ASSETS</b>		
Goodwill	65 672	3 849
Other intangible fixed assets	158 073	93 086
Tangible fixed assets	15 166	7 123
Financial fixed assets	12 281	4 487
Inventories	34 551	28 598
Accounts receivable	27 292	19 513
Current tax assets	2 381	-
Other current receivables	9 011	6 290
Liquid funds	24 871	41 234
<b>Total assets</b>	<b>349 298</b>	<b>204 180</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>		
Shareholders' equity, attributable to the Parent Company's shareholders	316 414	184 874
Provisions	3 044	3 725
Current tax liabilities	-	1 574
Accounts payable	12 563	3 650
Other short-term non interest-bearing liabilities	17 277	10 357
<b>Total shareholders' equity and liabilities</b>	<b>349 298</b>	<b>204 180</b>

## CONSOLIDATED KEY RATIOS

	January - December		October - December	
	2016	2015	2016	2015
Gross margin non-Durable goods, %	80	78	80	80
Gross margin, %	74	71	75	75
EBITDA, %	12	16	9	21
Operating margin, %	2	6	0	12
Net margin, %	1	4	-2	9
Equity/assets ratio, %	91	91	91	91
Income per share, SEK	0,07	0,24	-0,02	0,13
Shareholders' equity per share, SEK	13,40	8,59	13,40	8,59
Share price on closing day, SEK	88,00	58,50	88,00	58,50

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

# CONSOLIDATED CASH FLOW STATEMENTS

SEKTHOUSANDS	January - December		October - December	
	2016	2015	2016	2015
Income after financial items	2 993	7 398	-105	3 672
Adjustment for items not affecting cash flow	14 727	11 510	4 624	3 365
Paid taxes	-4 528	-3 438	-122	-920
Change in inventories	-2 379	-1 130	-636	2 723
Change in trade receivables	-8 219	-6 025	-11 816	-8 530
Change in trade payables	9 956	263	1 896	2 599
<b>Cash flow from operating activities</b>	<b>12 550</b>	<b>8 578</b>	<b>-6 159</b>	<b>2 909</b>
Cash flow from investing activities	-29 725	-14 290	-9 374	-4 197
Cash flow from financing activities	244	-1 468	-	-
<b>Cash flow for the period</b>	<b>-16 931</b>	<b>-7 180</b>	<b>-15 533</b>	<b>-1 288</b>
Liquid funds at beginning of period	41 234	48 203	40 053	42 596
Exchange rate difference in liquid funds	568	211	351	-74
<b>Liquid funds at end of period</b>	<b>24 871</b>	<b>41 234</b>	<b>24 871</b>	<b>41 234</b>

# CONSOLIDATED CHANGES IN SHAREHOLDERS EQUITY

SEKTHOUSANDS	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, 2015</b>	<b>550</b>	<b>154 466</b>	<b>6 349</b>	<b>17 055</b>	<b>0</b>	<b>178 420</b>
Total comprehensive income Jan - December 2015			2 791	5 131		7 922
Paid in capital for share warrant program		101				101
Repurchase of warrants				-1 569		-1 569
<b>Shareholders' equity as of 31 December, 2015</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 - December 2016			4 201	1 501		5 702
Paid in capital for share warrant program		244				244
Acquisition of subsidiary	51	121 099			7 426	128 576
Acquisition from non-controlling interest	3	5 543		-539	-7 426	-2 419
Deduction of incremental costs directly related to issuing new shares net of tax		-563				-563
Change in reserves for development cost			11 405	-11 405		-
<b>Shareholders' equity as of 31 December, 2016</b>	<b>604</b>	<b>280 890</b>	<b>24 746</b>	<b>10 174</b>	<b>0</b>	<b>316 414</b>



# CONSOLIDATED INCOME STATEMENTS PER QUARTER

SEKTHOUSANDS	Oct - Dec 2016	Jul - Sep 2016	Apr - Jun 2016	Jan-Mar 2016	Oct - Dec 2015	Jul - Sep 2015	Apr - Jun 2015	Jan - Mar 2015
Net sales	38 418	31 730	34 498	33 531	32 680	26 618	29 127	31 820
Cost of goods sold	-9 530	-7 494	-9 639	-9 279	-8 055	-7 528	-7 397	-12 305
<b>Gross income</b>	<b>28 888</b>	<b>24 236</b>	<b>24 859</b>	<b>24 252</b>	<b>24 625</b>	<b>19 090</b>	<b>21 730</b>	<b>19 515</b>
Selling expenses	-10 312	-9 770	-8 105	-7 521	-9 095	-6 878	-8 707	-7 372
Administrative expenses	-6 751	-5 418	-5 883	-6 437	-3 384	-3 035	-3 495	-3 240
Research and development costs	-11 028	-9 033	-8 651	-7 958	-7 877	-7 513	-7 433	-8 262
Other operating revenues and expenses	-771	-747	-556	-560	-475	-129	-396	-456
<b>Operating income</b>	<b>26</b>	<b>-732</b>	<b>1 664</b>	<b>1 776</b>	<b>3 794</b>	<b>1 535</b>	<b>1 699</b>	<b>185</b>
Financial income and expenses	-131	97	365	-72	-122	381	-127	55
<b>Income after financial items</b>	<b>-105</b>	<b>-635</b>	<b>2 029</b>	<b>1 704</b>	<b>3 672</b>	<b>1 916</b>	<b>1 572</b>	<b>240</b>
Taxes	-475	82	-509	-590	-874	-579	-526	-289
<b>Net income</b>	<b>-580</b>	<b>-553</b>	<b>1 520</b>	<b>1 114</b>	<b>2 798</b>	<b>1 337</b>	<b>1 046</b>	<b>-49</b>
<b>Attributable to</b>								
Parent Company's shareholders	-580	-535	1 520	1 114	2 798	1 337	1 046	-49
Non-controlling interests	-	-18	-	-	-	-	-	-
	<b>-580</b>	<b>-553</b>	<b>1 520</b>	<b>1 114</b>	<b>2 798</b>	<b>1 337</b>	<b>1 046</b>	<b>-49</b>
Earnings per share, SEK	-0,02	-0,02	0,07	0,05	0,13	0,06	0,05	0,00
Earnings per share, SEK*	-0,02	-0,02	0,07	0,05	0,13	0,06	0,05	0,00
Average number of outstanding shares	23 614 088	23 609 412	21 534 958	21 512 769	21 512 769	21 512 769	21 512 769	21 512 769
Average number of outstanding shares*	23 829 088	23 824 412	21 534 958	21 512 769	21 512 769	21 512 769	21 512 769	21 707 769
Number of shares at closing day	23 614 088	23 614 088	23 531 941	21 512 769	21 512 769	21 512 769	21 512 769	21 512 769
Number of shares at closing day*	23 829 088	23 829 088	23 531 941	21 512 769	21 512 769	21 512 769	21 512 769	21 707 769
<b>EBITDA</b>	<b>3 586</b>	<b>2 737</b>	<b>4 759</b>	<b>4 870</b>	<b>6 881</b>	<b>4 440</b>	<b>4 597</b>	<b>2 883</b>
Amortization	-2 618	-2 628	-2 558	-2 553	-2 504	-2 557	-2 547	-2 546
Depreciation	-942	-841	-537	-541	-583	-348	-351	-152
<b>Operating income</b>	<b>26</b>	<b>-732</b>	<b>1 664</b>	<b>1 776</b>	<b>3 794</b>	<b>1 535</b>	<b>1 699</b>	<b>185</b>

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

# STATEMENTS OF COMPREHENSIVE INCOME

SEKTHOUSANDS	Oct - Dec 2016	Jul - Sep 2016	Apr - Jun 2016	Jan-Mar 2016	Oct - Dec 2015	Jul - Sep 2015	Apr - Jun 2015	Jan - Mar 2015
<b>Net income</b>	<b>-580</b>	<b>-553</b>	<b>1 520</b>	<b>1 114</b>	<b>2 798</b>	<b>1 337</b>	<b>1 046</b>	<b>-49</b>
<b>Other comprehensive income</b>								
<i>Items that may be reclassified to the income statement</i>								
Exchange rate differences	2 586	847	2 285	-1 060	-182	549	-2 201	4 980
Tax attributable to items that have been transferred, or can be transferred to net income	-230	-71	-225	69	19	-11	207	-543
<b>Total other comprehensive income, net after tax</b>	<b>2 356</b>	<b>776</b>	<b>2 060</b>	<b>-991</b>	<b>-163</b>	<b>538</b>	<b>-1 994</b>	<b>4 437</b>
<b>Total comprehensive income</b>	<b>1 776</b>	<b>223</b>	<b>3 580</b>	<b>123</b>	<b>2 635</b>	<b>1 875</b>	<b>-948</b>	<b>4 388</b>
<b>Attributable to</b>								
Parent Company's shareholders	1 776	241	3 580	123	2 635	1 875	-948	4 388
Non-controlling interests	-	-18	-	-	-	-	-	-
	<b>1 776</b>	<b>223</b>	<b>3 580</b>	<b>123</b>	<b>2 635</b>	<b>1 875</b>	<b>-948</b>	<b>4 388</b>

# INCOME STATEMENTS FOR THE PARENT COMPANY

SEKTHOUSANDS	January - December		October - December	
	2016	2015	2016	2015
Net sales	85 719	80 761	20 947	18 171
Cost of goods sold	-20 648	-19 065	-5 289	-2 377
<b>Gross income</b>	<b>65 071</b>	<b>61 696</b>	<b>15 658</b>	<b>15 794</b>
Selling expenses	-17 996	-19 804	-4 356	-5 874
Administrative expenses	-17 514	-9 431	-5 078	-1 866
Research and development costs	-35 144	-31 090	-10 554	-8 496
Other operating revenues and expenses	-3 174	-1 540	-1 388	-554
<b>Operating income</b>	<b>-8 757</b>	<b>-169</b>	<b>-5 718</b>	<b>-996</b>
Financial income and expenses	2 839	1 661	1 396	-208
<b>Income after financial items</b>	<b>-5 918</b>	<b>1 492</b>	<b>-4 322</b>	<b>-1 204</b>
Year end dispositions	4 025	-	4 025	-
Taxes	101	-464	395	674
<b>Net income</b>	<b>-1 792</b>	<b>1 028</b>	<b>98</b>	<b>-530</b>

Depreciation and amortization has reduced income for the period by SEK 12 401 thousand (11 211), of which SEK 3 253 thousand (2 876) for the quarter.

# BALANCE SHEETS FOR THE PARENT COMPANY

SEKTHOUSANDS	Dec 31, 2016	Dec 31, 2015
<b>ASSETS</b>		
Balanced expenditures for development	91 136	91 797
Patents and licences	1 675	1 268
Trademarks	16	21
Tangible fixed assets	11 501	6 127
Participation in affiliated companies	160 182	14 475
Other financial fixed assets	1 410	1 179
Inventories	13 521	7 129
Current tax assets	1 326	-
Accounts receivable	6 089	4 338
Receivables from affiliated companies	17 859	32 924
Other current receivables	8 057	5 721
Cash and bank	13 730	32 111
<b>Total assets</b>	<b>326 502</b>	<b>197 090</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>		
Shareholders' equity	297 426	173 147
Untaxed reserves	8 213	12 238
Provisions	1 237	1 033
Accounts payable	9 223	1 956
Current tax liabilities	-	746
Other short-term liabilities	10 403	7 970
<b>Total shareholders' equity and liabilities</b>	<b>326 502</b>	<b>197 090</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.

The Parent Company's distributable earnings are impacted by changes in the Swedish Annual Accounts Act, which means that the same amount as development expenditure which is capitalized in the Parent Company as from 2016 must be transferred from retained earnings to the restricted Reserve for Development Costs fund. This fund should be gradually run down as and when development expenditure impacts the income statement, for example due to amortization. No new or revised accounting policies that became effective in 2016 have had any significant impact on the Group.

## NOTE 2. SHARE WARRANT PROGRAMS

In total there are 427,000 outstanding warrants in two programs. If all the warrants are exercised to subscribe for shares, the share capital will increase by around SEK 11,000 and the number of shares will increase by 427,000 shares in total, corresponding to dilution of approximately 1.8 percent of the total number of shares and votes. Share warrant program 2015/2017 consists of 215,000 warrants and in June 2017 each warrant will entitle the holder to subscribe for one new share at a price of SEK 60.92. 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.

## NOTE 3. FINANCIAL DATA PER SEGMENT, GROUP

SEK THOUSANDS	January - December					
	Net sales of non-Durable goods		Durable goods		Total consolidated	
	2016	2015	2016	2015	2016	2015
Net sales	122 527	105 977	15 650	14 268	138 177	120 245
Cost of goods sold	-24 798	-23 826	-11 144	-11 459	-35 942	-35 285
<b>Gross income</b>	<b>97 729</b>	<b>82 151</b>	<b>4 506</b>	<b>2 809</b>	<b>102 235</b>	<b>84 960</b>

SEK THOUSANDS	October - December					
	Net sales of non-Durable goods		Durable goods		Total consolidated	
	2016	2015	2016	2015	2016	2015
Net sales	34 552	29 139	3 866	3 541	38 418	32 680
Cost of goods sold	-6 936	-5 877	-2 594	-2 178	-9 530	-8 055
<b>Gross income</b>	<b>27 616</b>	<b>23 262</b>	<b>1 272</b>	<b>1 363</b>	<b>28 888</b>	<b>24 625</b>

## NOTE 4. FINANCIAL INSTRUMENTS

The Group's financial assets and liabilities valued at acquisition value amount to SEK 56 (62) million and SEK 30 (16) million respectively. Fair value of the Group's financial assets and liabilities is assessed to correspond to the book value.

## NOTE 5. BUSINESS COMBINATIONS

On June 7, 2016 XVIVO Perfusion acquired 94.7 percent of the shares and 96.8 percent of the series 2015/2016 warrants in the listed company Vivoline Medical AB for SEK 138.1 million. The acquisition was paid for through the company's own shares in the amount of SEK 121.2 million and through a cash payment of SEK 16.9 million. On June 20, XVIVO Perfusion acquired a further 2.5 percent of the shares and 2.1 percent of the series 2015/2016 warrants in the listed company Vivoline Medical AB for SEK 3.4 million. The acquisition on June 20 was paid for through the company's own shares in the amount of SEK 2.9 million and through a cash payment of SEK 0.4 million. On July 14, XVIVO Perfusion acquired a further 1.6 percent of the shares and 0.7 percent of the series 2015/2016 warrants in Vivoline Medical AB for SEK 2.5 million. The acquisition on July 14 was paid for through the company's own shares in the amount of SEK 2.2 million and through a cash payment of SEK 0.3 million.

The compulsory redemption process was initiated by XVIVO Perfusion. Vivoline's shares and warrants were delisted from Nasdaq First north on July 8, 2016. During November XVIVO Perfusion acquired another 1.4 percent of the shares in the listed company Vivoline Medical AB. The acquisition during November was paid for through a cash payment of SEK 1.7 million. XVIVO Perfusion is consequently the owner of 100 percent of the shares and 99.6 percent of the warrants. Acquisition expenses attributable to the acquisition amounted to SEK 4.5 million and have been charged to "Administrative expenses" in the consolidated income statement during the year. Transaction costs that are directly attributable to the new issue of shares have been charged against equity and amounts to SEK 0.6 million net after tax.

Vivoline Medical AB operates in the field of lung transplantation and has research collaboration with Professor Stig Steen and Igelösa in the field of heart transplantation. The combined company creates more resources and competence to take Professor Stig Steen's world-leading research in the field of heart transplantation to a commercial phase. Furthermore, when market approval has been obtained, there will be opportunities for a rapid introduction onto the market thanks to XVIVO Perfusion's well-developed global sales and market organization. The acquisition also strengthens XVIVO Perfusion's market position in the field of lung transplantation in Europe and Australia, and enables synergies in clean room production, product development, regulatory issues, and marketing. The acquisition is in line with XVIVO Perfusion's strategic objective of becoming the leader in thorax transplantation.

The acquisition date is 7 July, 2016, but result and cash flow is included in the consolidated accounts from 30 June, 2016, since transactions up to this date are deemed to be immaterial to the consolidated accounts. If the acquisition had been done on 1 January, 2016 the consolidated pro forma accounts for the twelve months period January-December, 2016, shows net sales amounting to SEK 140.9 million and net income amounting to SEK -7.6 million. These amounts have been calculated using Vivoline Medical's income statement adjusted for possible differences in accounting principles between the group and the subsidiary.

The table below shows the acquisition analysis.

<b>Acquired intangible assets</b>	Fair Value (TSEK)
Paid purchase price as at 7 June, 2016	138 058
Fair value of non-controlling interests	7 426
<b>Total</b>	<b>145 484</b>
Capitalised development expenditure	62 423
Patent, licences and trademarks	1 023
Tangible fixed assets	2 553
Deferred tax assets	9 470
Inventories	616
Accounts receivable and other receivables	1 895
Liquid funds	9 776
Accounts payable and other liabilities	-3 752
Fair value of acquired net assets	84 004
Goodwill	61 480
<b>Total</b>	<b>145 484</b>

<b>Impact on the Group's cash flow</b>	Fair Value (TSEK)
Purchase price, paid in cash	17 344
Less: Cash and cash equivalents in acquired company	-9 776
<b>Impact on the Group's cash and cash equivalents</b>	<b>7 569</b>

## 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

SEKTHOUSANDS	January - December 2016	January - December 2015	October - December 2016	October - December 2015
<b>Operating income</b>	<b>2 734</b>	<b>7 212</b>	<b>26</b>	<b>3 794</b>
Amortization	10 357	10 155	2 618	2 504
Depreciation	2 861	1 434	942	583
<b>EBITDA</b>	<b>15 952</b>	<b>18 801</b>	<b>3 586</b>	<b>6 881</b>

### GROSS MARGIN

SEKTHOUSANDS	January - December 2016	January - December 2015	October - December 2016	October - December 2015
<i>Operating income</i>				
Net sales	138 177	120 245	38 418	32 680
Operating expenses				
Cost of goods sold	-35 942	-35 285	-9 530	-8 055
<b>Gross income</b>	<b>102 235</b>	<b>84 960</b>	<b>28 888</b>	<b>24 625</b>
<b>Gross margin %</b>	<b>74</b>	<b>71</b>	<b>75</b>	<b>75</b>

### GROSS MARGIN NON-DURABLE GOODS

SEKTHOUSANDS	January - December 2016	January - December 2015	October - December 2016	October - December 2015
<i>Operating income</i>				
Net sales of non-Durable goods	122 527	105 977	34 552	29 139
Operating expenses				
Cost of non-Durable goods sold	-24 798	-23 826	-6 936	-5 877
<b>Gross income, non-Durable goods</b>	<b>97 729</b>	<b>82 151</b>	<b>27 616</b>	<b>23 262</b>
<b>Gross margin, non-Durable goods %</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

SEKTHOUSANDS	Dec 31, 2016	Dec 31, 2015
Shareholders' equity	316 414	184 874
Total assets	349 298	204 180
<b>Equity/assets ratio %</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

**GROSS MARGIN NON-DURABLE GOODS, %**  
Gross income segment non-Durable goods as a percentage of the net sales of segment non-Durable goods.

**GROSS MARGIN, %**  
Gross income as a percentage of the net sales for the period.

**EBITDA MARGIN, %**  
Operating income before depreciation and amortization as a percentage of net sales for the period.

**OPERATING MARGIN, %**  
Operating income as a percentage of net sales for the period.

**NET MARGIN, %**  
Income for the period as a percentage of net sales for the period.

**EQUITY/ASSETS RATIO, %**  
Shareholders' equity and non-controlling interests as a percentage of total assets.

**SHAREHOLDERS' EQUITY PER SHARE, SEK**  
Shareholders' equity in relation to the number of shares outstanding at closing day.

**EARNINGS PER SHARE, SEK**  
Income for the period in relation to the average number of outstanding shares for the period.

**EARNINGS PER SHARE AFTER DILUTION, SEK**  
Income for the period in relation to the average number of outstanding shares after dilution for the period.

# 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.

**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.

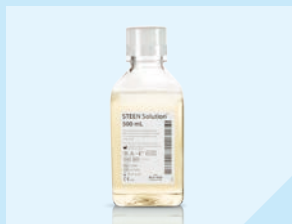
**HDE OR HUMANITARIAN DEVICE EXEMPTION**  
A humanitarian device exemption (HDE) application can be submitted to the FDA for a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States 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.

# PRODUCTS



## **XPS™**

SALES TYPE  
Warm Perfusion  
Durable Goods



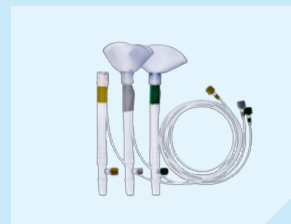
## **STEEN Solution™**

SALES TYPE  
Warm Perfusion



## **XPS Disposable Kit™**

SALES TYPE  
Warm Perfusion



## **XVIVO Lung Cannula Set™**

SALES TYPE  
Warm Perfusion



## **XVIVO Organ Chamber™**

SALES TYPE  
Warm Perfusion



## **XPS PGM Disposable Sensors™**

SALES TYPE  
Warm Perfusion



## **PERFADEX®**

SALES TYPE  
Cold Perfusion



## **Silicone Tubing Set™**

SALES TYPE  
Cold Perfusion



## **LS™**

SALES TYPE  
Warm Perfusion  
Durable Goods



## **DLS™**

SALES TYPE  
Warm Perfusion



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