



# REPORT ON OPERATIONS 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.*



# THE YEAR ENDED WITH CONTINUED STRONG GROWTH AND GOOD EBITDA

## FOURTH QUARTER 2018 (OCT - DEC)

- Total net sales in the quarter amounted to SEK 58.4 (41.6) million, corresponding to an increase of 40 percent in SEK and 33 percent in local currency. Net sales of non-durable goods\* in the quarter amounted to SEK 52.3 (39.4) million, corresponding to an increase of 33 percent in SEK and 26 percent in local currency.
- Warm perfusion sales of non-durable goods\*\* showed a record growth of more than 50 percent during the quarter. Sales from warm perfusion represented 50 percent (43) of sales of non-durable goods.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 10.5 (8.6) million, corresponding to an EBITDA margin of 18 percent. In comparison the operating income before depreciation and amortization (EBITDA) for the same quarter of 2017, excluding items affecting comparability, amounted to SEK 9.1 million.
- Operating income amounted to SEK 6.1 (4.7) million, after amortization and depreciation of SEK 4.4 (3.8) million.
- Net income amounted to SEK 4.9 (5.6) million, resulting in earnings per share of SEK 0.19 (0.21).
- Cash flow from operating activities was SEK 2.4 (7.9) million; mainly affected by higher working capital due to strong sales in the quarter.
- 4 XPS™ machines were delivered in the quarter.

## THE PERIOD 2018 (JAN - DEC)

- Total net sales in the period amounted to SEK 187.9 (148.3) million, corresponding to an increase of 27 percent in SEK and 23 percent in local currency. Net sales of non-durable goods\* in the period amounted to SEK 172.7 (141.0) million, corresponding to an increase of 22 percent in SEK and 19 percent in local currency.
- Sales from warm perfusion\*\* represented 43 percent (35) of sales of non-durable goods. The growth of sales from warm perfusion was about 50 percent for the period.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 30.9 (22.0) million, corresponding to an EBITDA margin of 16 percent. In comparison for the same period of 2017, the operating income before depreciation and amortization (EBITDA), excluding items affecting comparability, amounted to SEK 24.8 million.
- Operating income amounted to SEK 14.0 (7.1) million, after amortization and depreciation of SEK 16.9 (14.9) million.
- Net income amounted to SEK 12.7 (6.3) million, resulting in earnings per share of SEK 0.48 (0.25).
- Cash flow from operating activities was SEK 23.6 (22.2) million.
- SEK 19 million share issue as a result of warrants being exercised.
- PMA application for STEEN Solution™ and XPS™ was filed with the FDA.
- Perfadex® Plus, an upgraded version of Perfadex®, has been launched in Europe and the USA with successful adoption and positive feedback from clinicians and customers.
- Analysis of the PrimECC®-study showed that the product is safe and showed positive clinical results.
- United Therapeutics and XVIVO Perfusion executed a collaboration in which United Therapeutics intends to use XVIVO Perfusion's products in their organ assessment services.
- 8 XPS™ and LS™ were delivered during the period. At the end of the period 49 hospitals had access to either XPS™ or LS™.

## EVENTS AFTER THE PERIOD

- The Nomination Committee of XVIVO Perfusion proposes to the Annual General meeting April 25, 2019 re-election of the Board members Gösta Johannesson, Camilla Öberg, Yvonne Mårtensson, Alan Raffensperger and Folke Nilsson, and proposes Dag Andersson as a new Board member for 2019.

## CONFERENCE CALL

CEO Magnus Nilsson will present the report in a conference call at 2 p.m. CET on Friday, February 8, 2019.  
Telephone UK: +44 (0) 3333 0008 04 or USA: +1 631 913 1422, enter code 61837473#.

## MILESTONES PASSED DURING THE YEAR

- Perfadex® Plus has been launched in the United States. 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.
- United Therapeutics and XVIVO Perfusion executed a collaboration in which United Therapeutics purchased 2 XPS™ during the year.
- PMA application for STEEN Solution™ and XPS™ was filed with the FDA.
- The PrimECC® study showed that the product is safe and showed positive clinical results.
- Q4 of 2018 was the first quarter where sales of non-durable goods exceeded SEK 50 million.
- Q4 of 2018 was the first quarter where sales of warm perfusion represented 50 percent of sales of non-durable goods.

## CEO'S COMMENTS



During 2018 we made solid progress in XVIVO Perfusion's most important product area – warm perfusion of lungs. Highlights included unique upgrades of the XPS™ perfusion system, more clinics adopted the XPS™ technology, collaboration was expanded with United Therapeutics (an innovative player in the field of lung evaluation), and the organization for both clinical support and clinical trials was strengthened. These positive developments, in parallel with our ongoing investments in the business, enabled an increase in sales of approximately 50 percent for warm perfusion products. I am pleased to report that warm perfusion products now account for 50 percent of sales in the fourth quarter. A PMA application for XPS™ with STEEN Solution™ (warm perfusion) was submitted to the FDA is currently being evaluated. XVIVO Perfusion continues to have a good dialogue with the FDA on this matter.

Another important development milestone that was reached during 2018 relates to Perfadex® Plus. Perfadex® Plus is an improved "ready to use" version of Perfadex® which has been the company's highest volume selling product, the product was approved for sale and was subsequently launched in Europe and the US. In addition, a patent application has been submitted. Perfadex® Plus has been well received by the clinics as it simplifies usage and increases patient safety.

We are pleased that the company has managed to generate a good gross margin and profit at the same time as the major investments in R&D, regulatory competence and expansion of the organization for customer support have been made to enable continued good growth in the longer term as well.

At the same time the company took some very important steps during the year regarding the development of the future

growth areas. One clear example of this is ex-vivo perfusion and preservation of the heart in addition to PrimECC® – a product for the priming of heart-lung machines. This advancement was made possible due to the planned major investments in these areas which have created a strong and competent development organization equipped to meet the challenges involved in the establishing of these growth areas. Amongst other things, the new transportable heart preservation machine was successfully completed and preclinically tested and an application for a multicenter trial was submitted for this machine. In parallel, the company has intensified production development of the new unique heart preservation solution. Furthermore, analysis of the clinical study on PrimECC® has demonstrated that the product is safe and shown promising clinical results. This has spurred the company to set up large-scale production of the product and prepare a major multicenter study to further clinically document use of PrimECC®.

The focus in the time ahead for the lung transplantation area is to continue expanding the installation base of the company's EVLP (Ex Vivo Lung Perfusion) machines. In parallel it will be equally important to support clinics with technical and practical expertise by increasing resources for training and service provided to the clinics. The company will continue to develop the EVLP technology in order to support the transplantation surgeons in their efforts to be able to treat more of the patients on the waiting lists and to scientifically support a wider use of donated lungs.

XVIVO's research focus continues to put the patient first by continuing to lead the development of innovative solutions in the field of thoracic surgery in addition to developing the use of perfusion for more organs in transplantation.

Magnus Nilsson  
CEO

## FOURTH QUARTER 2018 (OCTOBER - DECEMBER)

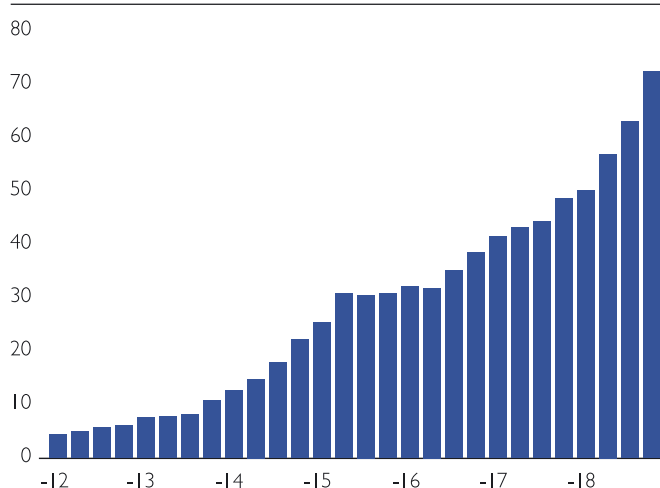
### Net Sales

Total net sales in the quarter amounted to SEK 58.4 (41.6) million, corresponding to an increase of 40 percent in SEK and

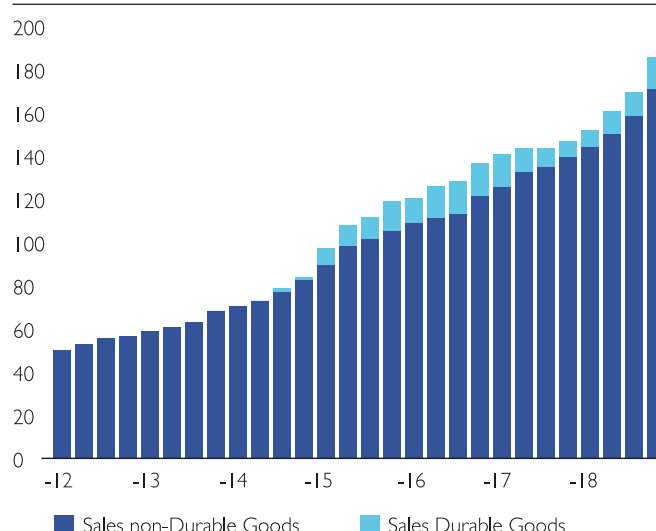
33 percent in local currency. Net sales of non-durable goods\* in the quarter amounted to SEK 52.3 (39.4) million, corresponding to an increase of 33 percent in SEK and 26 percent in local currency.

Total sales from warm perfusion (STEEN Solution™, XPS™, LS™, and products and services related to the use of the

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



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



## COMPILATION OF NET SALES AND EBITDA

SEK THOUSANDS	January - December		October - December	
	2018	2017	2018	2017
Net Sales non-Durable Goods	172 693	140 994	52 333	39 442
Net Sales Durable Goods	15 175	7 348	6 056	2 126
<b>Net Sales Total</b>	<b>187 868</b>	<b>148 342</b>	<b>58 389</b>	<b>41 568</b>
Cost of Goods non-Durable Goods	-39 406	-30 362	-11 521	-8 866
Cost of Goods Durable goods	-12 509	-4 584	-5 094	-865
Cost of Goods Total	-51 915	-34 946	-16 615	-9 731
Gross income non-Durable Goods	133 287	110 632	40 812	30 576
Gross margin non-Durable Goods, %	77%	78%	78%	78%
Gross income Durable Goods	2 666	2 764	962	1 261
Gross income Total	135 953	113 396	41 774	31 837
Gross margin Total, %	72%	76%	72%	77%
Selling expenses	-47 948	-43 702	-14 166	-10 819
Administrative expenses	-22 519	-20 045	-7 808	-5 391
Research and development costs	-47 931	-39 469	-12 560	-10 121
Other operating revenues and expenses	-3 555	-3 074	-1 126	-767
<b>Operating Income</b>	<b>14 000</b>	<b>7 106</b>	<b>6 114</b>	<b>4 739</b>
Depreciation of cost of goods sold	-527	-385	-177	-18
Depreciation of administrative expenses	-1 384	-985	-348	-378
Amortization of research and development expenses	-10 900	-10 559	-2 737	-2 646
Depreciation of other operative expenses	-4 112	-2 987	-1 109	-803
<b>EBITDA</b>	<b>30 923</b>	<b>22 022</b>	<b>10 485</b>	<b>8 584</b>
EBITDA, %	16%	15%	18%	21%
Items affecting comparability**	-	-2 802	-	-522
EBITDA excluding items affecting comparability	30 923	24 824	10 485	9 106
EBITDA excluding items affecting comparability, %	16%	17%	18%	22%



XPS™ and LS™) accounted for 55 (46) 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 50 (43) percent of the total sales of non-durable goods.

### Income

The gross margin for non-durable goods during the quarter was 78 (78) percent. The total gross margin during the quarter was 72 (77) percent. The decrease is mainly attributable to changes in segment mix.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 10.5 (8.6) million, corresponding to an EBITDA margin of 18 percent. In comparison the operating income before depreciation and amortization (EBITDA) for the same quarter 2017, excluding items affecting comparability, amounted to SEK 9.1 million.

Operating income amounted to SEK 6.1 (4.7) million, after amortization and depreciation of SEK 4.4 (3.8) million.

Selling expenses in relation to sales decreased during the quarter to 24 (26) percent. R&D expenses amounted to 22 (24) percent of sales. The decrease of selling and R&D expenses in relation to sales is primarily attributable to scale advantages. Administrative expenses decreased to 13 (13) percent of sales. Net of other operating revenues and expenses during the quarter were SEK -1.1 (-0.8) million.

During the quarter, SEK 12.1 (8.8) million of the development costs were capitalized as an intangible asset. SEK 2.9 (2.6) million was attributable to the continued NOVEL study with STEEN Solution™ and XPS™ with the aim of PMA approval. SEK 8.6 (5.5) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, and SEK 0.6 (0.7) million was attributable to product development of the rest of the product portfolio. Amortization of capitalized development costs for the quarter amounted to SEK 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 -2.4 (7.9) million. The main reason for the decrease compared to the same period prior year is higher working capital due to strong sales during the quarter. Investments amounted to SEK 11.9 (13.5) million, whereof SEK 12.4 (9.2) million was invested in intangible assets and SEK 1.0 (4.1) million was invested in tangible assets. Cash flow from sales of tangible assets was SEK 1.5 million. Cash and cash equivalents at the end of the quarter amounted to SEK 187.1 (195.3) million.

## THE PERIOD 2018 (JANUARY - DECEMBER)

### Net Sales

Total net sales in the period amounted to SEK 187.9 (148.3) million, corresponding to an increase of 27 percent in SEK and 23 percent in local currency. Net sales of non-durable goods\* in the period amounted to SEK 172.7 (141.0) million, corresponding to an increase of 22 percent in SEK and 19 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 47 (39) percent of the total sales. Warm perfusion sales from non-durable goods (STEEN Solution™, products and services related to the use of the XPS™ and LS™) accounted for 43 (35) percent of the total sales of non-durable goods.

### Income

The gross margin for non-durable goods during the period was 77 (78) percent. The decrease against the comparable period is mainly attributable to changes in product mix. The total gross margin during the period was 72 (76) percent. The decrease is mainly attributable to changes in segment mix.

Operating income before depreciation and amortization (EBITDA) amounted to SEK 30.9 (22.0) 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 24.8 million.

Operating income amounted to SEK 14.0 (7.1) million, after amortization and depreciation of SEK 16.9 (14.9) million.

Selling expenses in relation to sales decreased during the period to 26 (29) percent. The decrease is primarily attributable to temporary vacancies in the sales organization and scale advantages. R&D expenses amounted to 26 (27) percent of sales. Administrative expenses decreased to 12 (14) percent of sales, mainly due to scale advantages from the increase of sales. Net of other operating revenues and expenses during the period were SEK -3.6 (-3.1) million.

During the period, SEK 47.2 (28.1) millions of the development costs were capitalized as intangible assets. SEK 19.0 (11.9) million was attributable to the continued NOVEL study with STEEN Solution™ and XPS™ with the aim of PMA approval. SEK 26.9 (14.7) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, and SEK 1.3 (1.6) million was attributable to product development of the product portfolio. Amortization of capitalized development costs for the period amounted to SEK 10.2 (9.9) million, of which SEK 9.9 (9.9) million was amortization of the HDE approval.

## Cash flow

Cash flow from operating activities amounted to SEK 23.6 (22.2) million. Investments amounted to SEK 53.2 (35.5) million, whereof SEK 48.0 (29.3) million was invested in intangible assets and SEK 6.7 (5.6) million was invested in tangible assets. Cash flow from sales of tangible assets was SEK 1.5 million. 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 187.1 (195.3) million.

## Financing

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

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

During the second quarter of 2018, XVIVO Perfusion submitted the PMA (Premarket Approval) application for the XPS™ with STEEN Solution™ to the FDA. The application is being processed and the dialogue with FDA is good. 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, an advisory panel convened by the FDA unanimously voted 10-0 that the XPS™ System with STEEN Solution™ met the requirements for HDE (Humanitarian Device Exemption) approval by proving safety and probable patient benefits. Consequently, 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. An HDE approval entails certain restrictions while a PMA approval does not entail any restrictions.

## Positive findings in the PrimECC® study

Several hundred thousand heart operations are performed in the world each year using a heart-lung machine. PrimECC® is a CE-marked and patent-protected solution developed to prime the heart-lung machine before open heart surgery and its special composition aims to reduce side effects from the use of heart-lung machine.

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, which was presented during the second quarter of 2018, shows that the product is safe and indicates interesting findings regarding decreased side effects when using PrimECC®.

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 possible reduced risk of kidney damage. Another positive effect showed in the study is that the use of PrimECC®, unlike standard solutions for priming of heart-lung machines, also reduced red blood cell destruction, so-called hemolysis. Hemolysis releases substances that are harmful to both kidneys and blood vessels and may be a problem during cardiovascular surgery. The results further verify that PrimECC® is a safe product to use. In order to expand the documentation of clinical use of PrimECC® and to spread the use of the solution the company has decided on further clinical 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 during 2018 and is expected to be available in all major markets within 12 months.

## United Therapeutics and XVIVO Perfusion announced collaboration

During 2018, Lung Bioengineering, a subsidiary of United Therapeutics, purchased two XVIVO Perfusion System (XPS™) machines for use in its Silver Spring EVLP facility to evaluate donated lungs for clinics who do not hold the capacity on its own to make EVLP assessments on initially refused organs. 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.

## 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 2019

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

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

In its research and development the company carries out work with the aim of developing the use of the STEEN Solution™ method for other organs and of developing other areas of use for the company's solution technology, such as warm perfusion of organs that are still in the body and the priming of heart-lung machines. An example of the latter is PrimECC®, a patented product that has been approved in Europe for the priming of heart-lung machines before open heart surgery and which has been developed with a view to decreasing the adverse effects when using this type of device. The company plans to increase the documentation of PrimECC® during 2019 by performing multicenter studies. Expenditure attributable to documentation of PrimECC® will be capitalized on an ongoing basis up until market launch.

## THE COMPANY IN BRIEF

### Operations

XVIVO Perfusion AB is a medical technology company which develops solutions and systems for selecting usable organs and maintaining them in optimal condition pending transplantation. Currently, the company's product, Perfadex®, has a market share of approximately 90 percent in the traditional preservation of lungs for transplantation. The company's products for warm perfusion, XPS™ and STEEN Solution™, have regulatory approval in all major markets in the world, and 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

Based on the world leading research of Professor Stig Steen and Igelösa, XVIVO Perfusion's heart transplantation competence center in Lund (Sweden) develops a machine and solutions for heart preservation. The products are developed to increase the availability of donated hearts so that more heart transplants can be performed and more patients can be given a last chance of a longer life. Future focus is to perform clinical multicenter studies and use the documentation of these studies as a basis for applications for regulatory approvals for the products on all major markets.

### Other indications

The company also invests in preclinical and clinical research in transplantation of liver and kidney and in perfusion of organs remaining in the body, for example, drug administration to isolated organs and priming solutions for heart-lung machines.

### Business concept

XVIVO Perfusion's business concept is to increase the survival rate of patients in need of an organ transplant by providing effective products that increase the availability and survival potential of organs once transplanted.

### Vision

The company's vision is that no one should have to die waiting for a new organ.

### Objective

The company's objective is to establish the perfusion of organs with STEEN Solution™ and other advanced solutions as the standard treatment in organ transplantation so that more of these life saving treatments can be performed.

### Strategy

XVIVO Perfusion's strategy is focused on increasing the number of organs available for transplantation. Through development of products for perfusion of organs and through clinical trials on all major markets in the world, XVIVO Perfusion shows that

perfusion of organs gives more organs available for transplantation and thus gives a larger number of patients a life-saving treatment.

## OTHER INFORMATION

### Organization and personnel

At the end of 2018, the number of employees was 37, of whom 16 were women and 21 were men. Of these, 21 people were employed in Sweden and 16 outside Sweden. In addition, the company uses around 10 consultants.

### Information on transactions with related parties

During the fourth quarter, one transaction with the Board member Folke Nilsson was conducted amounting to SEK 15 thousand. In total the company has paid Folke Nilsson SEK 39 thousand for consultancy services within the product development area during 2018.

### 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  
Martin Lewin, appointed by Eccenovo AB  
Joachim Spetz, appointed by Swedbank Robur  
Gösta Johannesson, Chairman of the Board

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

### Annual General Meeting and Annual Report

The Annual General Meeting of XVIVO Perfusion AB (publ) will be held on 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.

It is estimated that XVIVO Perfusion's Annual Report for 2018 will be available for download on XVIVO Perfusion's website during the week commencing Monday, April 1.

### Events after the end of the reporting period

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



## Certification

The Board and the CEO certify that the half-year report gives a true and fair view for the company's and the Group's business activities, financial position and results, and describes the essential risks and uncertainty factors that the company and the companies which are part of the Group face

Gothenburg  
February 8, 2019

Magnus Nilsson  
CEO

Gösta Johannesson  
Chairman of the Board

Camilla Öberg  
Board member

Folke Nilsson  
Board member

Yvonne Mårtensson  
Board member

Erik von Schenck  
Board member

Alan Raffensperger  
Board member

### **This report has not been reviewed by the company's auditors**

#### **Financial reports**

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

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 February 8, 2019 at 7.30 am.*

This is a translation of the Swedish version of the report. When in doubt, the Swedish wording prevails.

## CONDENSED CONSOLIDATED STATEMENT OF NET INCOME

SEK THOUSANDS	January – December		October – December	
	2018	2017	2018	2017
Net sales	187 868	148 342	58 389	41 568
Cost of goods sold	-51 915	-34 946	-16 615	-9 731
<b>Gross income</b>	<b>135 953</b>	<b>113 396</b>	<b>41 774</b>	<b>31 837</b>
Selling expenses	-47 948	-43 702	-14 166	-10 819
Administrative expenses	-22 519	-20 045	-7 808	-5 391
Research and development costs	-47 931	-39 469	-12 560	-10 121
Other operating revenues and expenses	-3 555	-3 074	-1 126	-767
<b>Operating income</b>	<b>14 000</b>	<b>7 106</b>	<b>6 114</b>	<b>4 739</b>
Financial income and expenses	3 498	346	1 208	763
<b>Income after financial items</b>	<b>17 498</b>	<b>7 452</b>	<b>7 322</b>	<b>5 502</b>
Taxes	-4 813	-1 192	-2 437	64
<b>Net income</b>	<b>12 685</b>	<b>6 260</b>	<b>4 885</b>	<b>5 566</b>
<b>Attributable to</b>				
Parent Company's shareholders	12 685	6 260	4 885	5 566
Non-controlling interests	-	-	-	-
	<b>12 685</b>	<b>6 260</b>	<b>4 885</b>	<b>5 566</b>
Earnings per share, SEK	0,48	0,25	0,19	0,21
Earnings per share, SEK*	0,48	0,24	0,19	0,21
Average number of outstanding shares	26 302 385	25 440 188	26 402 496	26 190 496
Average number of outstanding shares*	26 302 385	25 693 549	26 402 496	26 402 496
Number of shares at closing day	26 402 496	26 190 496	26 402 496	26 190 496
Number of shares at closing day*	26 402 496	26 402 496	26 402 496	26 402 496
<b>EBITDA</b>	<b>30 923</b>	<b>22 023</b>	<b>10 485</b>	<b>8 585</b>
Amortization	-10 861	-10 542	-2 725	-2 639
Depreciation	-6 062	-4 375	-1 646	-1 207
<b>Operating income</b>	<b>14 000</b>	<b>7 106</b>	<b>6 114</b>	<b>4 739</b>

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

## CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME

SEK THOUSANDS	January – December		October – December	
	2018	2017	2018	2017
<b>Net income</b>	<b>12 685</b>	<b>6 260</b>	<b>4 885</b>	<b>5 566</b>
<b>Other comprehensive income</b>				
<i>Items that may be reclassified to the income statement</i>				
Exchange rate differences	4 875	-5 187	1 126	509
Tax attributable to items that have been transferred, or can be transferred to net income	-473	464	-164	-27
<b>Total other comprehensive income, net after tax</b>	<b>4 402</b>	<b>-4 723</b>	<b>962</b>	<b>482</b>
<b>Total comprehensive income</b>	<b>17 087</b>	<b>1 537</b>	<b>5 847</b>	<b>6 048</b>
<b>Attributable to</b>				
Parent Company's shareholders	17 087	1 537	5 847	6 048
Non-controlling interests	-	-	-	-
	<b>17 087</b>	<b>1 537</b>	<b>5 847</b>	<b>6 048</b>

# CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK THOUSANDS	Dec 31, 2018	Dec 31, 2017
<b>ASSETS</b>		
Goodwill	65 614	65 273
Other intangible fixed assets	214 084	176 902
Property, plant and equipment	15 615	16 277
Financial assets	13 619	15 466
<b>Total non-current assets</b>	<b>308 932</b>	<b>273 918</b>
Inventories	36 387	30 703
Current receivables	54 229	38 597
Liquid funds	187 064	195 322
<b>Total current assets</b>	<b>277 680</b>	<b>264 622</b>
<b>Total assets</b>	<b>586 612</b>	<b>538 540</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>		
Shareholders' equity, attributable to the Parent Company's shareholders	540 477	504 332
Long-term non-interest-bearing liabilities	3 562	3 312
Short-term non-interest-bearing liabilities	42 573	30 896
<b>Total shareholders' equity and liabilities</b>	<b>586 612</b>	<b>538 540</b>

## CONSOLIDATED KEY RATIOS

	January – December		October – December	
	2018	2017	2018	2017
Gross margin non-Durable goods, %	77	78	78	78
Gross margin, %	72	76	72	77
EBITDA, %	16	15	18	21
Operating margin, %	7	5	10	11
Net margin, %	7	4	8	13
Equity/assets ratio, %	92	94	92	94
Income per share, SEK	0,48	0,25	0,19	0,21
Shareholders' equity per share, SEK	20,47	19,26	20,47	19,26
Share price on closing day, SEK	132,00	94,00	132,00	94,00

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

## CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

SEK THOUSANDS	January – December		October – December	
	2018	2017	2018	2017
Income after financial items	17 497	7 452	7 321	5 502
Adjustment for items not affecting cash flow	15 263	13 183	2 212	3 667
Paid taxes	628	-2 657	559	1 760
Change in inventories	-2 311	822	102	1 947
Change in trade receivables	-17 236	-1 013	-17 871	-8 705
Change in trade payables	9 786	4 404	5 304	3 718
<b>Cash flow from operating activities</b>	<b>23 627</b>	<b>22 191</b>	<b>-2 373</b>	<b>7 889</b>
Cash flow from investing activities	-53 198	-35 523	-11 910	-13 517
Cash flow from financing activities	19 204	184 798	0	33
<b>Cash flow for the period</b>	<b>-10 367</b>	<b>171 466</b>	<b>-14 283</b>	<b>-5 595</b>
Liquid funds at beginning of period	195 322	24 871	201 248	200 818
Exchange rate difference in liquid funds	2 109	-1 015	99	99
<b>Liquid funds at end of period</b>	<b>187 064</b>	<b>195 322</b>	<b>187 064</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 -Dec, 2017			-4 723	6 260		1 537
Share warrant program		347				347
Issuing of new shares after deduction of incremental costs directly related to issuing new shares net of tax	66	186 424				186 490
Acquisition from non-controlling interest				-518		-518
<b>Shareholders' equity as of 31 December, 2017</b>	<b>670</b>	<b>467 661</b>	<b>8 618</b>	<b>27 383</b>	<b>0</b>	<b>504 332</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 - Dec, 2018			4 402	12 685		17 087
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 31 December, 2018</b>	<b>675</b>	<b>486 860</b>	<b>13 020</b>	<b>39 922</b>	<b>0</b>	<b>540 477</b>

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

## CONDENSED CONSOLIDATED STATEMENT OF NET INCOME PER QUARTER

SEK THOUSANDS	Oct - Dec 2018	Jul - Sep 2018	Apr - Jun 2018	Jan - Mar 2018	Oct - Dec 2017	Jul - Sep 2017	Apr - Jun 2017	Jan - Mar 2017
Net sales	58 389	40 914	46 090	42 475	41 568	32 263	37 034	37 477
Cost of goods sold	-16 615	-9 876	-13 061	-12 363	-9 731	-7 004	-7 823	-10 388
<b>Gross income</b>	<b>41 774</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>
Selling expenses	-14 166	-11 846	-11 549	-10 387	-10 819	-10 384	-11 128	-11 371
Administrative expenses	-7 808	-5 513	-4 684	-4 514	-5 391	-4 662	-4 935	-5 057
Research and development costs	-12 560	-11 734	-12 100	-11 537	-10 121	-8 883	-10 537	-9 928
Other operating revenues and expenses	-1 126	-1 207	-697	-525	-767	-941	-646	-720
<b>Operating income</b>	<b>6 114</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>
Financial income and expenses	1 208	-803	1 315	1 778	763	-287	-79	-51
<b>Income after financial items</b>	<b>7 322</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>
Taxes	-2 437	164	-1 420	-1 120	64	-453	-796	-7
<b>Net income</b>	<b>4 885</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>Attributable to</b>								
Parent Company's shareholders	4 885	99	3 894	3 807	5 566	-351	1 090	-45
Non-controlling interests	-	-	-	-	-	-	-	-
	<b>4 885</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>
Earnings per share, SEK	0,19	0,00	0,15	0,15	0,21	-0,01	0,04	0,00
Earnings per share, SEK*	0,19	0,00	0,15	0,15	0,21	-0,01	0,04	0,00
Average number of outstanding shares	26 402 496	26 402 496	26 378 940	26 190 496	26 190 496	26 190 496	25 765 673	23 614 088
Average number of outstanding shares*	26 402 496	26 786 496	26 378 940	26 190 496	26 402 496	26 402 496	26 140 117	23 829 089
Number of shares at closing day	26 402 496	26 402 496	26 402 496	26 190 496	26 190 496	26 190 496	26 190 496	23 614 088
Number of shares at closing day*	26 402 496	26 879 496	26 402 496	26 190 496	26 402 496	26 402 496	26 402 496	23 829 089
<b>EBITDA</b>	<b>10 485</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>
Depreciation and amortization of intangible assets	-2 725	-2 736	-2 699	-2 701	-2 639	-2 631	-2 626	-2 646
Depreciation and amortization of fixed assets	-1 646	-1 733	-1 377	-1 306	-1 207	-1 057	-1 094	-1 017
<b>Operating income</b>	<b>6 114</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>

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

## CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME PER QUARTER

SEK THOUSANDS	Oct - Dec 2018	Jul - Sep 2018	Apr - Jun 2018	Jan - Mar 2018	Oct - Dec 2017	Jul - Sep 2017	Apr - Jun 2017	Jan - Mar 2017
<b>Net income</b>	<b>4 885</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>Other comprehensive income</b>								
<i>Items that may be reclassified to the income statement</i>								
Exchange rate differences	1 126	-801	4 413	137	509	-2 276	-2 686	-735
Tax attributable to items that have been transferred, or can be transferred to net income	-164	81	-466	76	-27	210	245	36
<b>Total other comprehensive income, net after tax</b>	<b>962</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>Total comprehensive income</b>	<b>5 847</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>Attributable to</b>								
Parent Company's shareholders	5 847	-621	7 841	4 020	6 048	-2 417	-1 351	-744
Non-controlling interests	-	-	-	-	-	-	-	-
	<b>5 847</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>



## CONDENSED INCOME STATEMENT FOR THE PARENT COMPANY

SEK THOUSANDS	January – December		October – December	
	2018	2017	2018	2017
Net sales	152 332	123 345	40 997	35 660
Cost of goods sold	-39 735	-28 462	-10 941	-7 246
<b>Gross income</b>	<b>112 597</b>	<b>94 883</b>	<b>30 056</b>	<b>28 414</b>
Selling expenses	-27 940	-27 175	-8 395	-8 349
Administrative expenses	-12 578	-9 736	-5 000	-1 356
Research and development costs	-46 074	-38 955	-12 262	-9 607
Other operating revenues and expenses	-2 643	-3 899	-704	-1 055
<b>Operating income</b>	<b>23 362</b>	<b>15 118</b>	<b>3 695</b>	<b>8 047</b>
Financial income and expenses	6 460	-890	2 176	1 174
<b>Income after financial items</b>	<b>29 822</b>	<b>14 228</b>	<b>5 871</b>	<b>9 221</b>
Year end dispositions	-19 537	-3 900	-19 537	-3 900
Taxes	-2 487	-2 486	2 954	-1 384
<b>Net income</b>	<b>7 798</b>	<b>7 842</b>	<b>-10 712</b>	<b>3 937</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 14 053 thousand (13 320), of which SEK 3 467TSEK (3 397) for the quarter.

## CONDENSED BALANCE SHEET FOR THE PARENT COMPANY

SEK THOUSANDS	Dec 31, 2018	Dec 31, 2017
<b>ASSETS</b>		
Intangible fixed assets	149 153	111 697
Property, plant and equipment	7 367	10 713
Financial assets	200 222	203 474
<b>Total non-current assets</b>	<b>356 742</b>	<b>325 884</b>
Inventories	14 360	7 304
Current receivables	27 687	23 422
Cash and bank	178 248	173 421
<b>Total current assets</b>	<b>220 295</b>	<b>204 147</b>
<b>Total assets</b>	<b>577 037</b>	<b>530 031</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>		
Shareholders' equity	519 247	492 245
Untaxed reserves	10 150	8 913
Provisions	1 329	1 351
Short-term non-interest-bearing liabilities	46 311	27 522
<b>Total shareholders' equity and liabilities</b>	<b>577 037</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 significant need for extra impairment of assets due to expected credit losses.

### 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 outstanding 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 the end of the fourth quarter of 2018 two contracts existed with outstanding performance obligations. Revenue related to these performance obligations, 418 KSEK, has been postponed and is expected to be realized during the first quarter of 2019 in connection with the fulfillment of the 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, revenue for the current year would have been 230 KSEK higher and tax expense 51 KSEK higher, which would have resulted in a 179 KSEK higher equity at the period end.

### 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. 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 December 31, 2018, 279.000 were subscribed for and paid.

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.

During the period January-December 2018, neither the average share price nor the closing share price per December 31 exceeded the strike price of the two share warrant programs. Hence, none of the programs result in a dilution effect for existing shares.

## Note 3. Financial data per segment, group

SEK THOUSANDS	January – December					
	Net sales of non-Durable goods		Durable goods		Total consolidated	
	2018	2017	2018	2017	2018	2017
Net sales	172 693	140 994	15 175	7 348	187 868	148 342
Cost of goods sold	-39 406	-30 362	-12 509	-4 584	-51 915	-34 946
<b>Gross income</b>	<b>133 287</b>	<b>110 632</b>	<b>2 666</b>	<b>2 764</b>	<b>135 953</b>	<b>113 396</b>

SEK THOUSANDS	October – December					
	Net sales of non-Durable goods		Durable goods		Total consolidated	
	2018	2017	2018	2017	2018	2017
Net sales	52 333	39 442	6 056	2 126	58 389	41 568
Cost of goods sold	-11 521	-8 866	-5 094	-865	-16 615	-9 731
<b>Gross income</b>	<b>40 812</b>	<b>30 576</b>	<b>962</b>	<b>1 261</b>	<b>41 774</b>	<b>31 837</b>

## Note 4. Financial instruments

The Group's financial assets and liabilities valued at acquisition value amount to SEK 241 (229) million and SEK 42 (34) million respectively. Fair value of the Group's financial assets and liabilities is assessed to correspond to the book value.

# RECONCILIATION OF ALTERNATIVE KEY FIGURES

This report includes certain key ratios not defined in IFRS, but they are included in the report as company management considers that this information makes it easier for investors to analyze the Group's financial performance and position. Investors should regard these alternative key ratios as complementing rather than replacing financial information in accordance with IFRS.

## EBITDA

SEK THOUSANDS	Jan – Dec		Oct – Dec	
	2018	2017	2018	2017
<b>Operating income</b>	<b>14 000</b>	<b>7 106</b>	<b>6 114</b>	<b>4 739</b>
Depreciation and amortization of intangible assets	10 861	10 542	2 725	2 639
Depreciation and amortization of fixed assets	6 062	4 375	1 646	1 207
<b>EBITDA</b>	<b>30 923</b>	<b>22 023</b>	<b>10 485</b>	<b>8 585</b>

## Gross margin

SEK THOUSANDS	Jan – Dec		Oct – Dec	
	2018	2017	2018	2017
<i>Operating income</i>				
Net sales	187 868	148 342	58 389	41 568
<i>Operating expenses</i>				
Cost of goods sold	-51 915	-34 946	-16 615	-9 731
<b>Gross income</b>	<b>135 953</b>	<b>113 396</b>	<b>41 774</b>	<b>31 837</b>
<b>Gross margin %</b>	<b>72</b>	<b>76</b>	<b>72</b>	<b>77</b>

## Gross margin non-durable goods

SEK THOUSANDS	Jan – Dec		Oct – Dec	
	2018	2017	2018	2017
<i>Operating income</i>				
Net sales of non-durable goods	172 693	140 994	52 333	39 442
<i>Operating expenses</i>				
Cost of non-durable goods sold	-39 406	-30 362	-11 521	-8 866
<b>Gross income, non-durable goods</b>	<b>133 287</b>	<b>110 632</b>	<b>40 812</b>	<b>30 576</b>
<b>Gross margin, non-durable goods %</b>	<b>77</b>	<b>78</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	Dec 31, 2018	Dec 31, 2017
Shareholders' equity	540 477	504 332
Total assets	586 612	538 540
<b>Equity/assets ratio %</b>	<b>92</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	WARM PERFUSION	ACCESSORIES	COLD PERFUSION
 <p>XPS™, Durable goods</p>  <p>XPS Disposable Kit™</p>	 <p>LS™, Durable goods</p>  <p>LS Disposable Kit™</p>	 <p>STEEN Solution™</p>  <p>XVIVO Organ Chamber™</p>  <p>XVIVO Lung Cannula Set™</p>	 <p>PERFADEX®</p>  <p>PERFADEX® PLUS</p>  <p>Silicone Tubing Set™</p>





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