

INTERIM REPORT JANUARY-JUNE 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 TM and STEEN Solution TM , 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 40 people at its headquarters in Gothenburg, Sweden, its office in Lund, Sweden, and its office for North & South America in Denver, CO, USA. The XVIVO share is listed on NASDAQ Stockholm and has the ticker symbol XVIVO.



GOOD SALES GROWTH AND IMPORTANT MILESTONES PASSED

SECOND QUARTER 2018 (APRIL - JUNE)

- Total net sales in the quarter amounted to SEK 46.1
 (37.0) million, corresponding to an increase of 24 percent.

 The increase corresponds to 23 percent in local currency.
 Net sales of non-durable goods in the quarter amounted to SEK 42.2 (36.4) million, corresponding to an increase of 16 percent in SEK. Sales of non-durable goods increased by 14 percent in local currency.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 8.1 (5.7) 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 6.2 million, corresponding to an EBITDA margin, excluding items affecting comparability, of 17 percent.
- Operating income amounted to SEK 4.0 (2.0) million, after amortization and depreciation of SEK 4.1 (3.7) million.
- Net income amounted to SEK 3.9 (1.1) million, resulting in earnings per share of SEK 0.15 (0.04).

- Cash flow from operating activities was SEK 13.1 (8.7) million.
- Sales from warm perfusion* represented 43 percent (31) of sales of non durable goods.
- 2 XPS™ were delivered during the quarter.
- 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 marketing approval (510k) in the USA was given by FDA.
- Analysis of the PrimECC®-study showed that the product is safe and showed positive clinical results.
- United Therapeutics and XVIVO Perfusion initiated a collaboration and United Therapeutics intends to use XVIVO Perfusion's products in their organ assessment services.
- SEK 19 million share issue as a result of warrants being exercised.

THE PERIOD 2018 (JANUARY - JUNE)

- Total net sales amounted to SEK 88.6 (74.5) million, corresponding to an increase of 19 percent. The increase corresponds to 20 percent in local currency. Net sales of non-durable goods for the period amounted to SEK 80.1 (70.0) million, corresponding to an increase of 14 percent in SEK. Sales of non-durable goods increased by 16 percent in local currency.
- Operating income before depreciation and amortization (EBITDA) amounted to SEK 15.2 (9.4) million, corresponding to an EBITDA margin of 17 percent. In comparison the operating income before depreciation and amortization (EBITDA) for the same period 2017, excluding items affecting comparability, amounted to SEK 11.3 million, corresponding to an EBITDA margin, excluding items affecting comparability, of 15 percent.

- Operating income amounted to SEK 7.1 (2.0) million, after amortization and depreciation of SEK 8.1 (7.4) million.
- Net income amounted to SEK 7.7 (1.0) million, resulting in earnings per share of SEK 0.29 (0.04).
- Cash flow from operating activities was SEK 22.3 (6.7) million.
- Sales from warm perfusion* represented 39 percent (33) of sales of non durable goods.
- Reimbursement codes (so called CPT codes) have been valid in the USA since I January, 2018. The new codes simplify the reimbursement process for hospitals on the American market.
- 4 XPS™ were delivered during the period. At the end of the quarter 47 hospitals had access to either XPS™ or LS™.

CONFERENCE CALL

CEO Magnus Nilsson will present the report in a conference call at 2.00 p.m. CET on Friday, July 20, 2018. Telephone UK: +44 (0) 203 139 4830 or USA: +1 718 873 9077, enter code 63381754#.

MILESTONES PASSED DURING THE QUARTER

PMA application for STEEN Solution $^{\text{TM}}$ and XPS $^{\text{TM}}$ submitted to the FDA.

The PrimECC® study shows that the product is safe and displays positive clinical results

A prototype of a new heart preservation machine has been developed and tested on living hearts.

Perfadex Plus, an upgraded version of Perfadex, has been launched in Europe and has been registered by the FDA (510k).

United Therapeutics and XVIVO Perfusion begin collaboration and United Therapeutics intends to use XVIVO Perfusion's products in its organ evaluation service.

CEO'S COMMENTS



We can note great progress in the second quarter regarding both existing products in the lung transplant field as well as in development projects for the new indications. Sales increased by 23 percent in local currency to SEK 46 million, which is yet another record quarter for the company, and as previously

this growth was accompanied by a solid profit margin. We were particularly pleased by the fact that most of the growth was due to the company's warm perfusion products.

At the same time as the increase in sales, the company passed several other important milestones. One is that the FDA has approved the new improved preparation Perfadex Plus for marketing in the US. Another is that analysis of the clinical study on PrimECC® showed that the product is safe and displayed positive clinical results. The heart transplant indication continues to be developed; amongst other things, a new prototype of the heart preservation machine has been produced for international clinical trials and it has been tested on living hearts. The heart solution production set-up develops according to plan.

The most important milestone was the submission of the PMA application in the US for STEEN Solution™ and XPS™ during the second quarter. This milestone was passed after six years' work on the company's largest multicenter study ever. The company has had HDE approval (Humanitarian Device Exemption) since 2004 and already markets the products in the US. But HDE approval has certain limitations and PMA approval would mean that these restrictions cease to apply and that clinics' reimbursement process would be facilitated.

Another significant and positive milestone for the company, which has the potential to significantly increase use of EVLP in the US, was the collaboration with United Therapeutics that was begun during the quarter. United Therapeutics is investing great resources in development in the lung transplant field and its subsidiary Lung Bioengineering entered into an agreement during the quarter to purchase XPS™ machines, one of which has already been delivered. United Therapeutics will also purchase equipment to evaluate donated lungs at its Maryland facility as a service for transplant clinics. Under the agreement the companies will also collaborate to promote use of EVLP services. The fact that United Therapeutics, which is a leader in the field of innovative and effective therapies for severe lung diseases, elected to collaborate with XVIVO Perfusion and use the company's products confirms that XVIVO Perfusion's technology is a leader in the area.

Looking ahead the company's focus in the lung transplant area is to expand XPS market coverage (above all in Europe), upgrade the XPS™ machines that have already been installed with more functionality, and promote further clinical development of organ evaluation. This is so as to support the transplant clinics in their efforts to increase the number of transplantations of donated lungs for the benefit of patients waiting for new lungs. In the heart transplant field, the aim is to complete and validate the machine and solution production in order to enable international multicenter studies. For PrimECC® the goal is to continue clinical studies in order to obtain approval in all important markets and strengthen the clinical documentation before launch. The focus of XVIVO Perfusion's research is to continue to lead the development of innovative solutions in the field of thorax surgery and to develop the use of perfusion in more organs for transplantation.

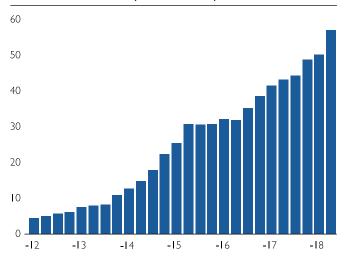
Magnus Nilsson CEO

SECOND QUARTER 2018 (APRIL - JUNE)

Net Sales

Total net sales in the quarter amounted to SEK 46.1 (37.0) million, corresponding to an increase of 24 percent in SEK and 23

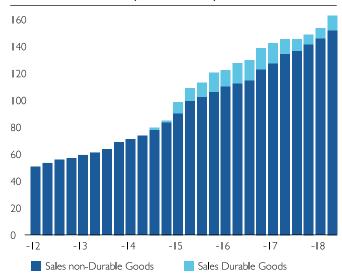
NET SALES WARM PERFUSION EXCL. DURABLE GOODS ROLLING 12-MONTHS (SEK MILLIONS)



percent in local currency. XVIVO Perfusion's net sales of non-durable goods* in the quarter amounted to SEK 42.2 (36.4) million, corresponding to an increase of 16 percent in SEK and 14 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 ROLLING 12 MONTHS (SEK MILLIONS)*



COMPILATION OF NET SALES AND EBITDA

		January - June		April - June	
SEK THOUSANDS	2018	2017	2018	2017	2017
Net Sales non-Durable Goods	80 109	69 979	42 244	36 402	140 994
Net Sales Durable Goods	8 456	4 532	3 846	632	7 348
Net Sales Total	88 565	74 511	46 090	37 034	148 342
Cost of Goods non-Durable Goods	-18 472	-14 492	-9 773	-7 823	-30 362
Cost of Goods Durable goods	-6 952	-3 719	-3 288	0	-4 584
Cost of Goods Total	-25 424	-18211	-13 061	-7 823	-34 946
Gross income non-Durable Goods	61 637	55 487	32 47 I	28 579	110 632
Gross margin non-Durable Goods, %	77%	79%	77%	79%	78%
Gross income Durable Goods	I 504	813	558	632	2 764
Gross income Total	63 141	56 300	33 029	29 211	113 396
Gross margin Total, %	71%	76%	72%	79%	76%
Selling expenses	-21 936	-22 499	-11 549	-11 128	-43 702
Administrative expenses	-9 198	-9 992	-4 684	-4 935	-20 045
Research and development costs	-23 637	-20 465	-12 100	-10 537	-39 469
Other operating revenues and expenses	-1 222	-1 366	-697	-646	-3 074
Operating Income	7 148	I 978	3 999	I 965	7 106
amortization and depreciation cost of goods sold	-199	-269	-141	-182	-385
depreciation administrative expenses	-534	-380	-227	-185	-985
amortization of research and development expenses	-5 414	-5 275	-2 706	-2 629	-10 559
depreciation other operative expenses	-1 936	-1 459	-1 002	-724	-2 987
EBITDA	15 23 1	9 361	8 075	5 685	22 022
EBITDA,%	17%	13%	18%	15%	15%
Items affecting comparability**	-	-1 915	0	-562	-2 802
EBITDA excluding items affecting comparability	15 231	11 276	8 075	6 247	24 824
EBITDA excluding items affecting comparability, $\!\%$	17%	15%	18%	17%	17%

 $^{4\} Interim\ Report\ January-June\ 2018\ XVIVO\ Perfusion\ AB, org.nr.\ 55656\ I-0424$

XPS™ and LS™) accounted for 47 (32) percent of the total sales. Warm perfusion sales from non-durable goods (STEEN Solution™, products and services related to the use of the XPS™ and LS™) accounted for 43 (31) percent of the total sales of non-Durable goods.

Income

Operating income before depreciation and amortization (EBITDA) amounted to SEK 8.1 (5.7) 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 6.2 million, corresponding to an EBITDA margin, excluding items affecting comparability, of 17 percent.

Operating income amounted to SEK 4.0 (2.0) million, after amortization and depreciation of SEK 4.1 (3.7) million.

The gross margin for non-Durable goods during the quarter was 77 (79) percent. The decrease against the comparable quarter is mainly attributable to changes in product mix. The total gross margin during the quarter was 72 (79) percent. The decrease is mainly attributable to changes in segment mix.

Selling expenses in relation to sales decreased during the quarter to 25 (30) percent. The decrease is primarily attributable to temporary vacancies in the sales organization but also scale advantages. Investments in the sales organization is planned during the upcoming quarters. R&D expenses amounted to 26 (28) percent of sales. The decrease is mainly effect of the post-ponement of non-capitalized R&D projects to the second half of 2018. Administrative expenses decreased to 10 (13) percent of sales, mainly due to extraordinary costs affecting comparability during 2017. Net other operating revenues and expenses during the quarter were SEK -0.7 (-0.6) million.

During the quarter, SEK 16.4 (6.3) million of the development costs were capitalized as an intangible asset. SEK 8.9 (2.2) million was attributable to the continued NOVEL study with STEEN Solution™ and XPS™ with the aim of PMA approval. SEK 7.5 (3.6) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, and SEK 0.0 (0.6) million was attributable to product development of the product portfolio. Depreciation and amortization for the quarter amounted to SEK 2.5 (2.5) million, of which SEK 2.5 (2.5) million was amortization of the HDE approval.

Cash flow

Cash flow from operating activities amounted to SEK 13.1 (8.7). Investments amounted to SEK 19.2 (6.5) million, whereof SEK 16.7 (6.4) million was invested in intangible assets and SEK 2.5 (0.1) million was invested in tangible assets. The cash flow from financing activities was SEK 19.3 (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 209 (203) million.

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

During the quarter, XVIVO Perfusion has submitted the PMA (Premarket Approval) application for the XPS™ with STEEN Solution™ to the FDA. The submission of the PMA application was the goal of a six-year effort with the company's largest multicenter study ever performed. The NOVEL Extension Clinical trial, that completed enrollment of 220 (110 + 110) patients in 2017 constitutes the basis of the company's PMA application. Around 40 percent of all lung transplants in the world are performed in the US. STEEN Solution™ and XPS™ are already approved for marketing in the US under a HDE (Humanitarian Device Exemption).

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

Positive findings in the PrimECC study

The PrimECC® study was completed during 2017, and was performed at Sahlgrenska University Hospital. The study included 80 (40 +40) patients randomized to have the heart-lung machine primed with either PrimECC® or the conventional, simpler solution currently used at the hospital. Analysis of the results shows that the product is safe and indicates interesting findings regarding decreased side effects when using PrimECC®.

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

To expand the documentation and spread the use of PrimECC®, the company has decided on further studies. PrimECC® is a CE-marked and patent-protected product, developed to prime the heart-lung machine before open heart surgery.

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), and it is currently being launched in European countries and is expected to be available in all major markets within 12 months.

United Therapeutics and XVIVO Perfusion announced collaboration

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

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) has during June 2018 increased by 212.000 shares and votes. The share issue of 212.000 shares raised approximately SEK 19 million before issue costs.

THE PERIOD 2018 (JANUARY – JUNE)

Net Sales

Total net sales in the period amounted to SEK 88.6 (74.5) million, corresponding to an increase of 19 percent in SEK and 20 percent in local currency. XVIVO Perfusion's net sales of non-durable goods* in the period amounted to SEK 80.1 (70.0) million, corresponding to an increase of 14 percent in SEK and 16 percent in local currency.

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

XPS™ and LS™) accounted for 45 (37) 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 39 (33) percent of the total sales of non-Durable goods.

Income

Operating income before depreciation and amortization (EBITDA) amounted to SEK 15.2 (9.4) million, corresponding to an EBITDA margin of 17 percent. In comparison the operating income before depreciation and amortization (EBITDA) for the same period 2017, excluding items affecting comparability, amounted to SEK 11.3 million, corresponding to an EBITDA margin, excluding items affecting comparability, of 15 percent.

Operating income amounted to SEK 7.1 (2.0) million, after amortization and depreciation of SEK 8.1 (7.4) million.

The gross margin for non-Durable goods during the period was 77 (79) percent. The decrease against the comparable period is mainly attributable to changes in product mix. The total gross margin during the period was 71 (76) percent. The decrease is mainly attributable to changes in segment mix.

Selling expenses in relation to sales decreased during the period to 25 (30) percent. The decrease is primarily attributable to temporary vacancies in the sales organization but also scale advantages. Investments in the sales organization is planned during the upcoming periods. R&D expenses amounted to 27 (27) percent of sales. Administrative expenses decreased to 10 (13) percent of sales, mainly due to extraordinary costs affecting comparability during 2017. Net other operating revenues and expenses during the period were SEK -1.2 (-1.4) million.

During the period, SEK 24.8 (12.0) million of the development costs were capitalized as an intangible asset. SEK 13.1 (5.0) million was attributable to the continued NOVEL study with STEEN Solution™ and XPS™ with the aim of PMA approval. SEK 11.7 (6.3) million was attributable to investments in the Heart transplant project with aim of marketing approval in the USA and Europe, and SEK 0.0 (0.7) million was attributable to product development of the product portfolio. Depreciation and amortization for the period amounted to SEK 5.1 (4.9) million, of which SEK 4.9 (4.9) million was amortization of the HDE approval.

Cash flow

Cash flow from operating activities amounted to SEK 22.3 (6.7). Investments amounted to SEK 30.0 (12.7) million, whereof SEK 25.4 (12.5) million was invested in intangible assets and SEK 4.6 (0.2) million was invested in tangible assets. The cash flow from financing activities was SEK 19.3 (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 209 (203) million.

^{*} See note 3 for revenue per segment.

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 93 (95) percent at the end of the period.

OUTLOOK FOR 2018

As the number of lungs that can be transplanted using traditional cold perfusion cannot be predicted to increase more than the number of lungs donated, it is expected that growth will come primarily from warm perfusion using the STEEN Solution™ method. The focus is therefore, to continue to develop the method with the aim of establishing the STEEN Solution™ method as the standard treatment for lung transplantation. The company will intensify clinical research and product development in cardiac transplantation. Expenses attributable to cardiac transplantation will be capitalized on an ongoing basis.

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

THE COMPANY IN BRIFE

Operations

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

Lung transplantation

A great problem in transplantation healthcare is the lack of available lungs. Currently in the USA, only around 20 percent of the available donated lungs are transplanted, as it is considered far too risky to transplant the remaining majority. By using XVIVO's product STEEN Solution™, the organ is cleared of harmful substances from the donor, thus creating a better environment for the organ's cells. The technology thereby allows the organ to "recover" when possible. It also allows for functional testing to be performed on the organ outside the body. In clinical use in the US, Europe, Australia, and Canada, it has emerged that once STEEN Solution™ perfusion has been carried out, many of the organs that were initially "rejected" are

assessed as being usable and have been successfully transplanted into patients with end-stage lung disease. Therefore, the use of STEEN Solution $^{\text{TM}}$ has the potential to increase the total number of lung transplants.

Heart transplantation

The center in Lund (Sweden) develops a machine and products for heart preservation. The products are designed to help increase the availability of donated hearts so that more heart transplants can be performed and more patients can be given a last chance of a longer life with better quality of life. The products are in the phase of pre-clinical studies and clinical proof of concept. Future focus is to take the products into the phase of clinical research and to reach regulatory approval for the products.

Other indications

The company conducts preclinical and clinical research in transplantation of organs other than lungs as well as and in perfusion of organs remaining in the body, for example, drug administration to isolated organs and priming solutions for heart-lung machines.

Business concept

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

Vision

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

Objective

The company's objective is to establish the warm perfusion of organs with XPS $^{\text{TM}}$ and STEEN Solution $^{\text{TM}}$ as the standard treatment in the transplantation of lungs and other organs.

Strategy

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

OTHER INFORMATION

Organization and personnel

At the end of quarter, the number of employees was 35, of whom 17 were women and 18 were men. Of these, 21 people were employed in Sweden and 14 outside Sweden. In addition, the company uses around 10 consultants.

Information on transactions with related parties

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

Risk management

XVIVO Perfusion is constantly working to identify, evaluate, and manage risks in different systems and processes. Risk analyses are performed continually with regard to the company's normal business activities and also in connection with activities that are outside XVIVO Perfusion's regular quality system.

The market risks that are determined to have particular importance for the future development of XVIVO Perfusion are access to financial funds and medical resources at clinics around the world. Operational risks primarily comprise risks that limit or prevent XVIVO Perfusion from developing, manufacturing and selling quality, effective and safe products. Legal and regulatory risks may arise from changes in legislation and other regulations. Changes in legislation or political decisions may affect the company's ability to run or develop the business. Including financial risks are the currency risk for the business.

The most important strategic and operative risks affecting the company are described in the 2017 annual report.

Seasonal effects

XVIVO Perfusion's sales are marginally affected by seasonal effects. Mainly in new treatments such as EVLP or warm perfusion of the lungs there are slightly less activity during the summer months.

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 of the parent company's and the Group's business activities, financial position and results and describes the essential risks and uncertainty factors that the parent company and the companies which are part of Group face.

Gothenburg July 20, 2018

Magnus Nilsson CEO Gösta Johannesson Chairman of the Board

Erik von Schenck Board member Folke Nilsson Board member

Camilla Öberg Board member Yvonne Mårtensson 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. Following reports are planned to be submitted:

Interim Report January-September 2018: Friday, October 26, 2018

Report on Operations 2018: Thursday, February 8, 2019

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 July 20, 2018 at 8.00 am.

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

CONDENSED CONSOLIDATED STATEMENT OF NET INCOME

SELVEL LOUISANIES	January – June		A A	Whole year	
SEK THOUSANDS	2018	2017	2018	2017	2017
Net sales	88 565	74 511	46 090	37 034	148 342
Cost of goods sold	-25 424	-18211	-13 061	-7 823	-34 946
Gross income	63 141	56 300	33 029	29 211	113 396
Selling expenses	-21 936	-22 499	-11 549	-11 128	-43 702
Administrative expenses	-9 198	-9 992	-4 684	-4 935	-20 045
Research and development costs	-23 637	-20 465	-12 100	-10 537	-39 469
Other operating revenues and expenses	-1 222	-1 366	-697	-646	-3 074
Operating income	7 148	I 978	3 999	I 965	7 106
Financial income and expenses	3 093	-130	1 315	-79	346
Income after financial items	10 241	I 848	5 314	I 886	7 452
Taxes	-2 540	-803	-1 420	-796	-1 192
Net income	7 701	I 045	3 894	I 090	6 260
Attributable to					
Parent Company's shareholders	7 701	I 045	3 894	1 090	6 260
Non-controlling interests	-	-	-	-	-
	7 701	I 045	3 894	I 090	6 260
Earnings per share, SEK	0,29	0,04	0,15	0,04	0,25
Earnings per share, SEK*	0,29	0,04	0,15	0,04	0,24
Average number of outstanding shares	26 290 607	24 689 880	26 378 940	25 765 673	25 440 188
Average number of outstanding shares*	26 290 607	24 984 603	26 378 940	26 40 17	25 693 549
Number of shares at closing day	26 402 496	26 190 496	26 402 496	26 190 496	26 190 496
Number of shares at closing day*	26 402 496	26 402 496	26 402 496	26 402 496	26 402 496
EBITDA	15 23 1	9 361	8 075	5 685	22 023
Amortization	-5 400	-5 272	-2 699	-2 626	-10 542
Depreciation	-2 683	-2	-1 377	-1 094	-4 375
Operating income	7 148	I 978	3 999	I 965	7 106

^{*} After dilution. See note 2 for information on warrant programs.

CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME

	Jä	anuary – June	Apr	April – June		
SEK THOUSANDS	2018	2017	2018	2017	2017	
Net income	7 701	I 045	3 894	1 090	6 260	
Other comprehensive income						
Items that may be reclassified to the income statement						
Exchange rate differences	4 550	-3 421	4413	-2 686	-5 187	
Tax attributable to items that have been transferred, or can be						
transferred to net income	-390	281	-466	245	464	
Total other comprehensive income, net after tax	4 160	-3 140	3 947	-2 441	-4 723	
Total comprehensive income	11 861	-2 095	7 841	-1 351	I 537	
Attributable to						
Parent Company's shareholders	11 861	-2 095	7 841	-1 351	I 537	
Non-controlling interests	-	-	-	-	-	
	11 861	-2 095	7 84 I	-1 351	I 537	

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK THOUSANDS	June 30, 2018	June 30, 2017	Dec 31, 2017
ASSETS			
Goodwill	65 608	65 382	65 273
Other intangible fixed assets	196 635	165 283	176 902
Property, plant and equipment	18 478	13 250	16 277
Financial assets	15 958	12 732	15 466
Total non-current assets	296 679	256 647	273 918
Inventories	28 964	33 077	30 703
Current receivables	41 963	37 151	38 597
Liquid funds	209 038	203 040	195 322
Total current assets	279 965	273 268	264 622
Total assets	576 644	529 915	538 540
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity, attributable to the Parent Company's shareholders	535 329	501 147	504 332
Long-term non-interest-bearing liabilities	3 299	3 164	3 3 1 2
Short-term non-interest-bearing liabilities	38 016	25 604	30 896
Total shareholders' equity and liabilities	576 644	529 915	538 540

CONSOLIDATED KEY RATIOS

	Ja	anuary – June		April – June		
	2018	2017	2018	2017	2017	
Gross margin non-Durable goods, %	77	79	77	79	78	
Gross margin, %	71	76	72	79	76	
EBITDA,%	17	13	18	15	15	
Operating margin, %	8	3	9	5	5	
Net margin,%	9	I.	8	3	4	
Equity/assets ratio, %	93	95	93	95	94	
Income per share, SEK	0,29	0,04	0,15	0,04	0,25	
Shareholders' equity per share, SEK	20,36	19,13	20,29	19,13	19,26	
Share price on closing day, SEK	115,00	99,00	115,00	99,00	94,00	

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

CONDENSED CONSOLIDATED CASH FLOW STATEMENTS

	Ja	inuary – June	Ар	April – June		
SEK THOUSANDS	2018	2017	2018	2017	2017	
Income after financial items	10 241	I 848	5 3 1 4	I 886	7 452	
Adjustment for items not affecting cash flow	9 475	6 197	5 780	2 574	13 183	
Paid taxes	651	-3 162	I 233	-2 264	-2 657	
Change in inventories	4 541	-726	I 35 I	619	822	
Change in trade receivables	-3 707	4 57 I	-2 488	I 990	-1013	
Change in trade payables	I 066	-2 024	1 921	3 9 1 9	4 404	
Cash flow from operating activities	22 267	6 704	13 111	8 724	22 191	
Cash flow from investing activities	-30 025	-12 667	-19 156	-6 452	-35 523	
Cash flow from financing activities	19 283	184 823	19 283	184 823	184 798	
Cash flow for the period	11 525	178 860	13 238	187 095	171 466	
		0.4.074				
Liquid funds at beginning of period	195 322	24 87 I	193 507	16515	24 87 I	
Exchange rate difference in liquid funds	2 191	-691	2 293	-570	-1 015	
Liquid funds at end of period	209 038	203 040	209 038	203 040	195 322	

CONSOLIDATED CHANGES IN SHAREHOLDERS EQUITY

		Attributable to Pa	arent Company's	s shareholders		
SEK THOUSANDS	Share capital	Other paid in capital	Reserves	Retained ear- nings incl. profit for the year	Non-controlling interests	Sum shareholders' equity
Shareholders' equity as of 1 January, 2017	604	280 890	13 341	21 641	0	316 476
Total comprehensive income Jan - June, 2017			-3 140	I 045		-2 095
Share warrent program Issuing of new shares efter deduction of incremental costs directly		347				347
related to issuing new shares net of tax	66	186 424				186 490
Shareholders' equity as of 30 June, 2017	670	467 661	10 201	22 686	0	501 218
Total comprehensive income July - December, 2017			-1 583	5 2 1 5		3 632
Acquisition from non-controlling interest				-518		-518
Shareholders' equity as of 31 december, 2017	670	467 661	8618	27 383	0	504 332
Retrospective adjustement*				-146		-146
Adjusted Shareholders Equity as of 31 december 2017	670	467 661	8618	27 237	0	504 186
Total comprehensive income January - June, 2018			4 159	7 70 I		11 860
Share warrent program Issuing of new shares efter deduction of incremental costs directly		182				182
related to issuing new shares net of tax	5	19 096				19 101
Shareholders' equity as of 30 june, 2018	675	486 939	12 777	34 938	0	535 329

^{*}Effect of the introduction of IFRS 15 "Revenue from contracts with costumers"

CONDENSED CONSOLIDATED STATEMENT OF NET INCOME PER QUARTER

SEK THOUSANDS	Apr - Jun 2018	Jan - Mar 2017	Oct - Dec 2017	Jul - Sep 2017	Apr - Jun 2017	Jan - Mar 2016	Oct - Dec 2016	Jul - Sep 2016
Net sales	46 090	42 475	41 568	32 263	37 034	37 477	38 418	31 730
Cost of goods sold	-13 061	-12 363	-9 731	-7 004	-7 823	-10 388	-9 530	-7 494
Gross income	33 029	30 112	31 837	25 259	29 211	27 089	28 888	24 236
Selling expenses	-11 549	-10 387	-10819	-10 384	-11 128	-11 371	-10312	-9 770
Administrative expenses	-4 684	-4514	-5 391	-4 662	-4 935	-5 057	-6 751	-5 418
Research and development costs	-12 100	-11 537	-10 121	-8 883	-10 537	-9 928	-11 028	-9 033
Other operating revenues and expenses	-697	-525	-767	-941	-646	-720	-771	-747
Operating income	3 999	3 149	4 739	389	I 965	13	26	-732
Financial income and expenses	1 315	I 778	763	-287	-79	-51	-131	97
Income after financial items	5 3 1 4	4 927	5 502	102	I 886	-38	-105	-635
Taxes	-1 420	-1 120	64	-453	-796	-7	-475	82
Net income	3 894	3 807	5 566	-351	I 090	-45	-580	-553
Attributable to								
Parent Company's shareholders	3 894	3 807	5 566	-351	1 090	-45	-580	-535
Non-controlling interests	-	_	-	-	-	-	-	-18
<u> </u>	3 894	3 807	5 566	-351	I 090	-45	-580	-553
Earnings per share, SEK	0,15	0,15	0,21	-0,01	0,04	0,00	-0,02	-0,02
Earnings per share, SEK*	0,15	0,15	0,21	-0.01	0,04	0,00	-0,02	-0,02
Average number of outstanding shares	26 378 940	26 190 496	26 190 496	26 190 496	25 765 673	23 614 088	23 614 088	23 609 412
Average number of outstanding shares*	26 378 940	26 190 496	26 402 496	26 402 496	26 40 17	23 829 089	23 829 089	23 824 412
Number of shares at closing day	26 402 496	26 190 496	26 190 496	26 190 496	26 190 496	23 614 088	23 614 088	23 614 088
Number of shares at closing day*	26 402 496	26 190 496	26 402 496	26 402 496	26 402 496	23 829 089	23 829 089	23 829 089
EBITDA	8 075	7 156	8 585	4 077	5 685	3 676	3 586	2 737
Amortization	-2 699	-2 701	-2 639	-2 631	-2 626	-2 646	-2618	-2 628
Depreciation	-1 377	-1 306	-1 207	-1 057	-1 094	-1017	-942	-841
Operating income	3 999	3 149	4 739	389	I 965	13	26	-732

 $[\]ensuremath{^{*}}$ After dilution. See note 2 for information on warrant programs.

CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME PER QUARTER

sek thousands	Apr - Jun 2018	Jan - Mar 2017	Oct - Dec 2017	Jul - Sep 2017	Apr - Jun 2017	Jan - Mar 2016	Oct - Dec 2016	Jul - Sep 2016
Net income	3 894	3 807	5 566	-351	I 090	-45	-580	-553
Other comprehensive income Items that may be reclassified to the income statement								
Exchange rate differences Tax attributable to items that have been transferred, or can be transferred to	4413	137	509	-2 276	-2 686	-735	2 586	847
net income	-466	76	-27	210	245	36	-230	-71
Total other comprehensive income,					-			
net after tax	3 947	213	482	-2 066	-2 441	-699	2 356	776
Total comprehensive income	7 84 I	4 020	6 048	-2 417	-1 351	-744	I 776	223
Attributable to								
Parent Company's shareholders	7 841	4 020	6 048	-2417	-1 351	-744	I 776	241
Non-controlling interests	-	-	-	-	-	-	-	-18
	7 841	4 020	6 048	-2 417	-1 351	-744	I 776	223

CONDENSED INCOME STATEMENT FOR THE PARENT COMPANY

	Ja	nuary – June	Apr	Whole year	
sek thousands	2018	2017	2018	2017	2017
Net sales	69 903	55 703	43 732	23 301	123 345
Cost of goods sold	-18 591	-14 399	-10 117	-5 009	-28 462
Gross income	51 312	41 304	33 615	18 292	94 883
Selling expenses	-13 084	-13 654	-6 025	-6 693	-27 175
Administrative expenses	-4 171	-6 298	-1 953	-3 148	-9 736
Research and development costs	-21 155	-20 449	-12 024	-10 533	-38 955
Other operating revenues and expenses	-1 107	-1 680	-452	-858	-3 899
Operating income	11 795	-777	13 161	-2 940	15 118
Financial income and expenses	5 184	-1 006	3 598	-1 037	-890
Income after financial items	16 979	-1 783	16 759	-3 977	14 228
Year end dispositions	-	-	-	-	-3 900
Taxes	-3 866	392	-3 782	875	-2 486
Net income	13 113	-1 391	12 977	-3 102	7 842

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 6 906 (6 028) thousand, of which SEK 3 447 thousand (3 307) for the quarter.

CONDENSED BALANCE SHEET FOR THE PARENT COMPANY

sek thousands	June 30, 2018	June 30, 2017	Dec 31, 2017
ASSETS			
Intangible fixed assets	131 566	100 089	111 697
Property, plant and equipment	9 564	10 115	10713
Financial assets	192 173	184 160	203 474
Total non-current assets	333 303	294 364	325 884
Inventories	10 368	8 279	7 304
Current receivables	22 096	19 415	23 422
Cash and bank	191 067	184 255	173 421
Total current assets	223 531	211 949	204 147
Total assets	556 834	506 313	530 03 I
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	524 642	482 975	492 245
Untaxed reserves	8913	8 2 1 3	8913
Provisions	I 338	I 358	I 35 I
Short-term non-interest-bearing liabilities	21 941	13 767	27 522
Total shareholders' equity and liabilities	556 834	506 313	530 031

Disclosures in accordance with IAS 34.16A occur in the financial statements and the related notes, as well as elsewhere in parts of the interim report.

Note 1. Accounting principles

For the Group, the report is presented pursuant to the Swedish Annual Accounts Act and IAS 34, Interim Financial Reporting, and for the Parent Company pursuant to the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities.

Accounting principles applied for the Group and the parent company correspond, unless otherwise stated below, with the accounting policies used for the preparation of the latest annual report.

During 2018 the Group has started to apply IFRS 9 Financial instruments and IFRS 15 Revenue from contracts with customers. The effects of the transition is presented below.

IFRS 9 Financial instruments

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

IFRS 15 Revenue from contracts with customers

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

The company's net sales are divided into three categories: sale of goods excluding capital goods, revenues from sale and rental of capital goods and finally revenues from freight, service and other sales (see note 2 in the company's most recent Annual Report). Sale of goods excluding capital goods and revenues from freight, service and other sales comprise products and services that clearly represent separate performance obligations. It is therefore assessed that for these there are not any significant differences between current accounting and accounting pursuant to IFRS 15.

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

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

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

IFRS 16 Leases

IFRS 16 "Leases" will as of 2019 replace existing IFRS related to the recognition of leasing agreements, such as IAS 17 "Leases" and IFRIC 4 "Determining Whether an Arrangement Contains a Lease". XVIVO will apply IFRS 16 as per January 1, 2019. As an operational lessee, the company will be impacted by the introduction of IFRS 16. Estimates in terms of figures of the effect of IFRS 16 and the choice of transitional methods have not yet been made. However, the information given in Note 10 of the company's most recent Annual Report gives an indication of the type and scope of the agreements that existed at 30 june 2018.

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 30 June, 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 30 June, 2018, 279,000 were subscribed for and paid.

If all warrants are exercised for subscription of shares, the share capital will increase by approximately SEK 13.000 and the number of shares will increase by a total of 558.000, corresponding to a dilution of approximately 2.1 percent of the total number of shares and votes. Warranty Program 2017/2019 consists of 243.000 warrants and each warrant entitle the holder to subscribe for a new share at a price of SEK 138.51 in May-June 2019. Warranty Program 2018/2020 consists of 315,000 warrants and each warrant in May-June 2020 entitles the holder to subscribe for a new share at a price of SEK 146.02.

During the period January – June 2018 neither the average share price nor the closing share price as of 30 June exceeded the strike price for each of the warrant programs. Hence no dilution effect has been calculated for the existing shares.

Note 3. Financial data per segment, group

		January - June							
	Net sales of non-Durable goods		Durable goods		Total consolidated				
SEK THOUSANDS	2018	2017	2018	2017	2018	2017			
Net sales	80 109	69 979	8 456	4 532	88 565	74 511			
Cost of goods sold	-18 472	-14 492	-6 952	-3719	-25 424	-18211			
Gross income	61 637	55 487	I 504	813	63 141	56 300			

	April - June					
	Net sales of		Durable		Total	
	non-Durab	ole goods	good	s	consoli	dated
SEK THOUSANDS	2018	2017	2018	2017	2018	2017
Net sales	42 244	36 402	3 846	632	46 090	37 034
Cost of goods sold	-9 773	-7 822	-3 288	0	-13 061	-7 822
Gross income	32 47 1	28 580	558	632	33 029	29 212

Note 4. Financial instruments

The Group's financial assets and liabilities valuated at acquisition value amount to SEK 244 (235) million and SEK 36 (26) 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

					vvnoie	
	Jan – Jun		Apr – Jun		year	
sek thousands	2018	2017	2018	2017	year 2017	
Operating income	7 148	I 978	3 999	I 965	7 106	
Amortization	5 400	5 272	2 699	2 626	10 542	
Depreciation	2 683	2 111	I 377	1 094	4 375	
EBITDA	15 231	9 361	8 075	5 685	22 023	

Gross margin

lar	n – lun	Δn	r – lun	Whole year
2018	2017	2018	2017	2017
88 565	74 511	46 090	37 034	148 342
-25 424	-18211	-13 061	-7 823	-34 946
63 141	56 300	33 029	29 211	113 396
71	76	72	79	76
	2018 88 565 -25 424 63 141	88 565 74 511 -25 424 -18 211 63 141 56 300	2018 2017 2018 88 565 74 511 46 090 -25 424 -18 211 -13 061 63 141 56 300 33 029	2018 2017 2018 2017 88 565 74 511 46 090 37 034 -25 424 -18 211 -13 061 -7 823 63 141 56 300 33 029 29 211

Gross margin non-Durable goods

Or oss margin non-burable goods					
_	_				Whole
	Jan – Jun		Apr – Jun		year
sek thousands	2018	2017	2018	2017	2017
Operating income					
Net sales of non-Durable					
goods	80 109	69 979	42 244	36 402	140 994
Operating expenses					
Cost of non-Durable goods					
sold	-18 472	-14 492	-9 773	-7 822	-30 362
Gross income,					
non-Durable goods	61 637	55 487	32 47 1	28 580	110 632
Gross margin,					
non-Durable goods %	77	79	77	79	78

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

Equity/assets ratio %	93	95	94
Total assets	576 644	529 915	538 540
Shareholders' equity	535 329	501 147	504 332
sek thousands	June 30, 2018	June 30, 2017	Dec 31, 2017

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
Gross margin non-Durable goods, %	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.
Gross margin, %	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.
EBITDA margin, %	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.
Operating margin, %	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.
Net margin, %	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.
Equity/assets ratio, %	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.
Shareholders' equity per share, SEK	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.
Earnings per share, SEK	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.
Earnings per share after dilution, SEK	Income for the period in relation to the average number of outstanding shares after dilution for the period.	The key ratio has been included to give investors an overview of how the company's equity per share after dilution has evolved.

GLOSSARY

The following explanations are intended to help the reader understand certain specific terms and expressions in XVIVO Perfusion's reports:

Preclinical study

Research performed before a drug or method of treatment is sufficiently documented to be studied in humans, for example the testing of substances in tissue samples and subsequent testing in experimental animals.

Clinical study/trial

An investigation in healthy or sick people to study the effect of a drug or method of treatment.

Medical device

Comprises devices used to diagnose a disease or treat a disease and as rehabilitation.

Obstructive lung disease

Disease where there is airway obstruction.

Perfusion

Passage of a fluid through an organ's blood vessels.

Evaluation

Evaluation of the function of an organ.

Preservation

Storage and maintenance of an organ outside the body before transplantation.

Ex vivo (Latin for "outside a living organism")

Biological processes in living cells and tissues when they are in an artificial environment outside the body."Opposite" of in vivo.

In vivo

Biological processes in living cells and tissues when they are in their natural place in intact organisms.

EVLP or Ex Vivo Lung Perfusion

Perfusion of a lung outside the body. The procedure is normally done to evaluate a lung before transplantation.

FDA or US Food and Drug Administration

The FDA is the USA's food and drug authority with responsibility for food, dietary supplements, drugs, cosmetics, medical equipment, radiology equipment, and blood products. FDA approval is required to market a medical device on the American market.

PMA or Premarket Approval

Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and efficacy of Class III medical devices. Class III devices support or sustain human life, are of substantial importance in preventing impairment of human health, or potentially present an unreasonable risk of illness or injury.

HDE or Humanitarian Device Exemption

A humanitarian device exemption (HDE) application can be submitted to the FDA for a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. An HDE is similar in both form and content to a Premarket Approval (PMA) application, but is exempt from the efficacy requirements of a PMA.

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 PERFUSIONS PRODUCTS





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