



# **ANNUAL REPORT 2018**

## XVIVO PERFUSION AB (PUBL)

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# XVIVO PERFUSION IN BRIEF

XVIVO Perfusion is a medical technology company which develops and markets innovative system solutions for the preservation and evaluation of donated organs outside the body awaiting transplantation.

XVIVO Perfusion was founded by Magnus Nilsson in 1998, when lung transplantation was a relatively new field. Since the company was started 20 years ago, XVIVO Perfusion has established collaboration with several world-leading researchers in the transplantation field. In parallel with this collaboration new technology and solutions have been developed with the aim of making more organs available for transplantation. XVIVO Perfusion is the market leader in the field of lung transplantation. We supply transplantation clinics worldwide with advanced technological products for the preservation and evaluation of lungs. The company employs just over 40 people at its headquarters in Gothenburg, Sweden in addition to subsidiaries in Lund, Sweden, and in Denver in the US.

We are dedicated to our vision of "No-one should die waiting for a new organ" and are proud that our groundbreaking innovations have contributed to more patients being able to receive a transplant, thus giving them the chance of a longer and better life. Together with leading researchers and transplantation clinics, XVIVO Perfusion contributes to developing solutions that make a difference – for the patient, the transplantation team and society.

XVIVO Perfusion's shares are listed on NASDAQ Stockholm and are traded under the ticker symbol XVIVO.

This is a translation from the Swedish version of the Annual report. If in doubt the swedish wording prevails.



# IMPORTANT EVENTS 2018

Foto: Pax Engström



**XVIVO Perfusion was awarded the 2018 Export Gazelle Prize by Dagens Industri and The Swedish Export Credit Agency (EKN).**

**20 YEARS**  
of NEW HORIZONS IN  
TRANSPLANTATION

**XVIVO Perfusion has been in existence as a company for 20 years, and this was celebrated during the year.**

- PMA application for STEEN Solution™ and the XPS™ submitted to the FDA.
- Perfadex® Plus launched in Europe and the US. The product is an improved ready-to-use version of Perfadex® which simplifies use and increases safety.
- The PrimECC® study demonstrated that the product is safe and displayed positive clinical data.
- XVIVO Perfusion's new prototype of the heart preservation machine underwent preclinical trials and the results of the trials were good.
- United Therapeutics and XVIVO Perfusion initiated collaboration and United Therapeutics' subsidiary Lung Bioengineering bought two XPS™.
- 8 XPS™ and XVIVO LS™ were delivered during the year. At the end of the year 49 clinics had access to the XPS™ or XVIVO LS™.
- The fourth quarter of 2018 was the first quarter in which warm perfusion accounted for 50 percent of sales, excluding non-disposable goods.
- Reimbursement codes (so-called CPT codes) have been in place in the US for the entire EVLP process since January 1, 2018. This simplifies the reimbursement process for hospitals in the American market.

## SALES OF NON-DURABLE GOODS

**+22%**

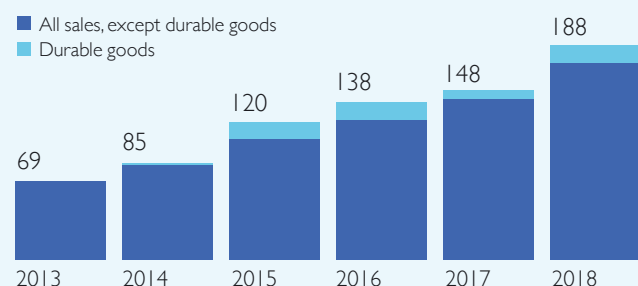
## PERCENTAGE WARM PERFUSION\*

**47%**

## EBITDA

**16%**

## SALES, SEK MILLIONS



## KEY RATIOS – THE GROUP

	2018	2017
Gross margin, non-durable goods, %	77	78
Gross margin, %	72	76
EBITDA, %	16	15
Operating margin, %	7	5
Net margin, %	7	4
Equity/assets ratio, %	92	94
Earnings per share, SEK	0,48	0,25
Equity per share, SEK	20,47	19,26
Share price at closing day, SEK	132,00	94,00

\*The percentage of warm perfusion is sales of products and services for warm perfusion (STEEN Solution™, the XPS™, the XVIVO LS™ and products and services related to use of the XPS™ and the XVIVO LS™) as a percentage of total sales of products and services.

# YET ANOTHER SUCCESSFUL YEAR

In 2018 XVIVO Perfusion celebrated its 20th anniversary as a company. Last year was characterized by strong growth and intense research and development work. The high growth rate accelerated towards the end of the year, driven by an increase in warm perfusion. During the year XVIVO Perfusion made large investments in R&D, regulatory competence and in customer support to ensure continued good growth in the longer term as well. At the same time the company generated a good gross margin and profit.

## Important progress in the warm perfusion of lungs

2018 was yet another successful and eventful year for XVIVO Perfusion and great progress was made in XVIVO Perfusion's most important product area – the warm perfusion of lungs. This included the launch of unique upgrades of the perfusion system XPS™, several clinics adopting the XPS™ technology, expansion of the collaboration with United Therapeutics (an innovative player in the field of lung evaluation) and a strengthening of the organization in the areas of clinical support and clinical trials. All this, together with existing investments, enabled an increase in sales of approximately 50 percent which resulted in warm perfusion achieving 50 percent of sales during the fourth quarter. A PMA application for the XPS™ with STEEN Solution™ was also submitted to the FDA during the year, and this is currently being evaluated by the authority. The company continues to have a good dialogue with the FDA in this area.

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

## Perfadex® Plus launched during the year

Another important milestone that was passed during the year. Perfadex® Plus, which is an improved "ready-to-use" version of Perfadex®, the company's largest product, was approved for marketing and was launched in Europe and the US. Perfadex® Plus is a unique preparation and a patent has been applied for the product. It was well received by clinics during the launch as it simplifies use and increases patient safety.

## Acceleration of the heart transplant and PrimECC® projects

In parallel with the company has maintaining a high rate of development in the field of lung transplantation, very important steps have been taken in the development of the future growth areas of heart transplantation and PrimECC®. This was possible due to increased investments in the development organization with the main focus in heart transplantation. Amongst other things the new transportable heart preservation machine was successfully completed and preclinically tested. As a follow up to this an application for multicenter trials on the machine was submitted. In parallel, the company has intensified production development of the new unique heart preservation solution.



Analysis of the PrimECC® clinical study demonstrated that the product is safe and displayed promising clinical results. This has encouraged the company to prepare for production and to prepare a major multicenter study so as to further clinically document the benefits of PrimECC® for patients.

## Outlook for 2019: Focus on leading global development of organ perfusion

The focus for XVIVO moving head within the lung transplantation area is to continue expanding the installation base of the company's EVLP (Ex Vivo Lung Perfusion) machines in addition to supporting clinics with technical and practical expertise. This effort will be supported by increasing resources for training and service provided to the clinics. The company will also continue to develop the EVLP technology in order to support transplantation surgeons in their efforts to be able to treat more of the patients on the waiting list though scientifically supporting a wider use of donated lungs from even infected or heart-dead donors. XVIVO's research focuses on continuing to lead the development of innovative solutions in the field of thorax surgery and on developing the use of perfusion for more organs in transplantation.

## A big thank you

Finally, I would like to say a big thank you to our employees and partners. Thanks to your hard work, our company has passed several important milestones that have brought us many steps closer to our vision that no-one should need to die while waiting for a new organ.

Magnus Nilsson  
CEO

# 20 YEARS OF INNOVATION

The current business in XVIVO Perfusion stems from Perfadex®, a product for cold preservation of lungs that Magnus Nilsson acquired the rights to in 1998. The same year Magnus Nilsson began collaboration with Professor Stig Steen at Lund University regarding the development of a new technology for warm perfusion of lungs, with the aim of making more organs available for transplantation. This collaboration resulted in STEEN Solution™. In 2006 STEEN Solution™ was approved in Europe.

During the years up until 2007, Perfadex® was established as standard treatment in the preservation of lungs. From 2008 to 2014 intensive work was carried out to develop the

XPST™, which is a machine for warm perfusion, and to attain approval of the XPS™ and STEEN Solution™ in all major markets. During 2014 the XPS™ was approved in Europe and the XPS™ with STEEN Solution™ received HDE approval from the FDA for sales in the US. Today the product portfolio for warm perfusion is approved in all major markets in the world. In order to strengthen XVIVO Perfusion's product and research portfolio, the company acquired Vivoline Medical AB in June 2016. XVIVO Perfusion's product portfolio was then strengthened by the LS™ system and XVIVO took control of an advanced development project for the preservation and evaluation of hearts.

## 1998

Perfadex® acquired.

Development collaboration started with Professor Steen, with the aim of making use of more organs.

## 1999

Development collaboration started with Doctor Shaf Keshavjee in Toronto with the aim of obtaining market approval for Perfadex® in the US.

## 2000

Professor Steen performs the first transplantation of a lung from a heart-dead donor using STEEN Solution™. Publication in The Lancet.

## 2001

Perfadex® obtains market approval in the US and gradually increases its market share.

## 2006

STEEN Solution™ approved for use in Europe.

## 2007

First patent for STEEN Solution™ approved in the US.

## 2010

HELP study in Canada completed. The good clinical results are published in the New England Journal of Medicine in 2011.

## 2011

The clinical NOVEL study is initiated at several leading transplantation clinics in the US.

## 2012

XVIVO Perfusion AB is distributed to Vitrolife's shareholders and listed on NASDAQ OMX First North.

XVIVO Perfusion Inc started and takes over sales and distribution to the Americas.

## 2013

The first lung transplantation in Asia of a lung treated using the STEEN Solution™ method is performed at Okayama University Hospital in Japan.

## 2014

FDA HDE approval of the XPS™ and STEEN Solution™ after the FDA's expert panel votes unanimously that the XPS™ and STEEN Solution™ meet the requirements for HDE approval.

The XPS™ system obtains a CE mark, thus enabling sales in Europe.

## 2015

First liver transplant using STEEN Solution™ performed.

STEEN Solution™ approved for marketing and clinical use in China.

## 2016

PrimECC® obtains CE mark and a patent, and a clinical study is initiated.

Vivoline Medical AB and its advanced heart transplantation solution acquired.

## 2017

First heart transplant using Prof. Steen's method performed.

CPT reimbursement codes obtained for the entire EVLP process in the US.

## 2018

PMA application for the XPS™ and STEEN Solution™ submitted to FDA.

Perfadex® Plus, a ready-to-use solution, launched.

PrimECC® study demonstrates that the product is safe and displays positive clinical results.



# BUSINESS CONCEPT, OBJECTIVES AND STRATEGIES

More and more people are prepared to donate their organs both in Sweden and globally. However, there is still a great shortage of organs available. According to the WHO just over 135,000 organ transplantations are carried out worldwide each year, but this corresponds to only 10% of the need. The shortage of organs means that many patients die while waiting for an organ, or their condition deteriorates to such an extent that they are removed from the waiting list. In the US alone it is estimated that 20 people die each day while waiting for a new organ. XVIVO Perfusion develops and markets solutions and systems to evaluate organs and keep them in optimal condition pending transplantation, thus making more organs available for transplantation.

## Business concept

XVIVO Perfusion's business concept is to increase survival rates for patients requiring a transplant by providing effective products that increase the availability of organs that have good potential to survive after transplantation.

## Corporate vision

Our vision is that "no-one should die while waiting for a new organ".

## Business objective

The company's objective is to maintain its position as the market leader in the field of lung transplantation and to establish the perfusion of organs using STEEN Solution™ and other advanced solutions as standard treatment for the transplantation of lungs and other organs.

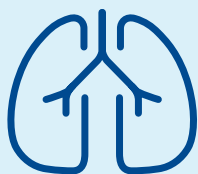
## Strategy

XVIVO Perfusion's strategy focuses on increasing the number of organs available for transplantation by supplying products and technology that allow organs to be preserved, evaluated and improved outside the body. The company and partners have demonstrated in published clinical studies that the warm perfusion of organs using the STEEN Solution™ method results in more available organs and thus more patients receive life-saving treatment. This means that fewer people on the waiting list die and also leads to a better quality of life and socioeconomic benefits.

## Objectives for 2019

- Continue to establish the XPS™ and STEEN Solution™ in the world.
- Begin clinical multicenter study for heart transplantation.
- Expand clinical documentation for PrimECC® through multicenter studies.

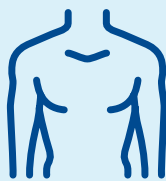
## BUSINESS AREAS



Lung transplantation



Heart transplantation



Other indications  
and organs

## OUR STRENGTHS

### Leader in the field of lung transplantation

- Perfadex® and Perfadex® Plus are established as standard treatment in traditional cold preservation of donated lungs before transplantation and have a market share of approximately 90% worldwide.
- XVIVO Perfusion was first in the world to develop a method to make use of more organs: warm perfusion using the XPS™ and STEEN Solution™. This method enables testing of pulmonary function outside the body. Today the product portfolio for warm perfusion is approved in all major markets in the world.
- XVIVO Perfusion is a strong brand in the field of lung transplantation.

### Established network in the field of thorax surgery

- XVIVO Perfusion has established relations with world-leading researchers and transplantation clinics.
- XVIVO Perfusion has a global market presence and an established distribution network.

### Experts in advanced solutions for transplantation

- XVIVO Perfusion, together with Igelösa Life Science and Professor Stig Steen, has developed unique solutions to take care of organs outside the body.
- XVIVO Perfusion continuously develops advanced solutions to increase the benefits for patients and customers, which Perfadex® Plus is an example of.

### Profitable growth

- XVIVO Perfusion has displayed growth and positive EBITDA every quarter since the share was listed in October 2012.

### Successful organization for innovations

The company has extensive experience of research and development, of the process of obtaining regulatory approval, and subsequently of different phases of establishment in the market. The following are particularly worthy of mention:

- XVIVO Perfusion's products, the XPS™ and STEEN Solution™, were the first products ever to obtain market approval in the US for warm perfusion of organs outside the body.
- XVIVO Perfusion's unique products for heart transplantation have been developed and are ready for regulatory studies.
- PrimECC®, a unique patented and CE marked product for priming of heart-lung machines, has been developed and clinically tested.

# ORGAN DONATION – THE GIFT OF LIFE

An organ donor can save up to 8 other people through the transplantation of the heart, lungs, kidneys, liver, pancreas and intestines. During 2016, 135,860 transplantations were carried out globally from 34,854 donors, according to GODT (Global Observatory on Donation and Transplantation). Even though the number of donors is increasing, it is only an estimated 10% of the need for transplantations that is met.

## DBD - Donation after brain death

Most organs that are transplanted come from patients with brain damage who are being cared for in a respirator and have been declared dead according to neurological criteria, so-called brain death. The concept of brain death has been crucial for organ donation and transplantation surgery. In transplantation from brain-dead donors, the supply of blood and oxygen to the organs is maintained, which facilitates the donation process. Furthermore, there is plenty of time to talk with relatives and to take care of the organs.

## DCD – Donation after circulatory death

The shortage of brain-dead donors has meant that heart-dead donors have successfully begun to be used in recent years. This has also meant that more people have been offered the opportunity to donate their organs after their death. In donations after heart-death, the donation process must go much quicker from the time of death until when the donation operation is begun. If

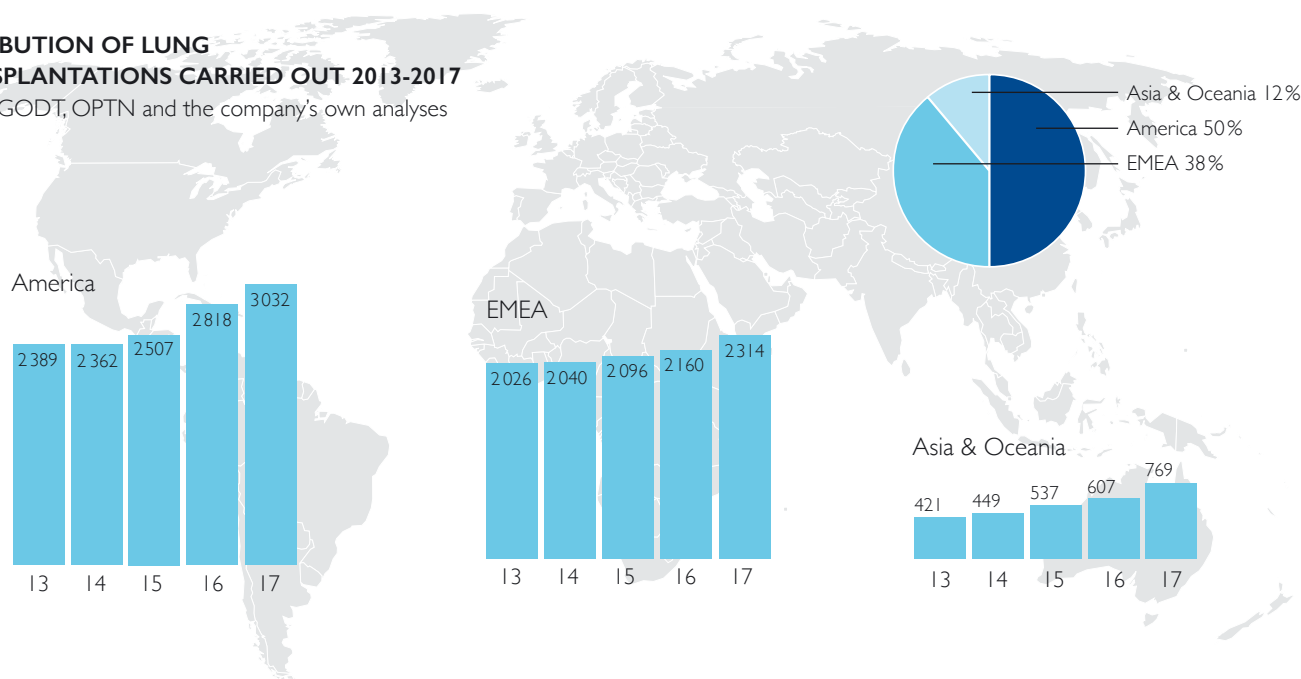
the process takes too long, the organs are unusable and generally speaking the uncertainty regarding the function of these donated organs is usually greater.

## Extended/Expanded Criteria Donation

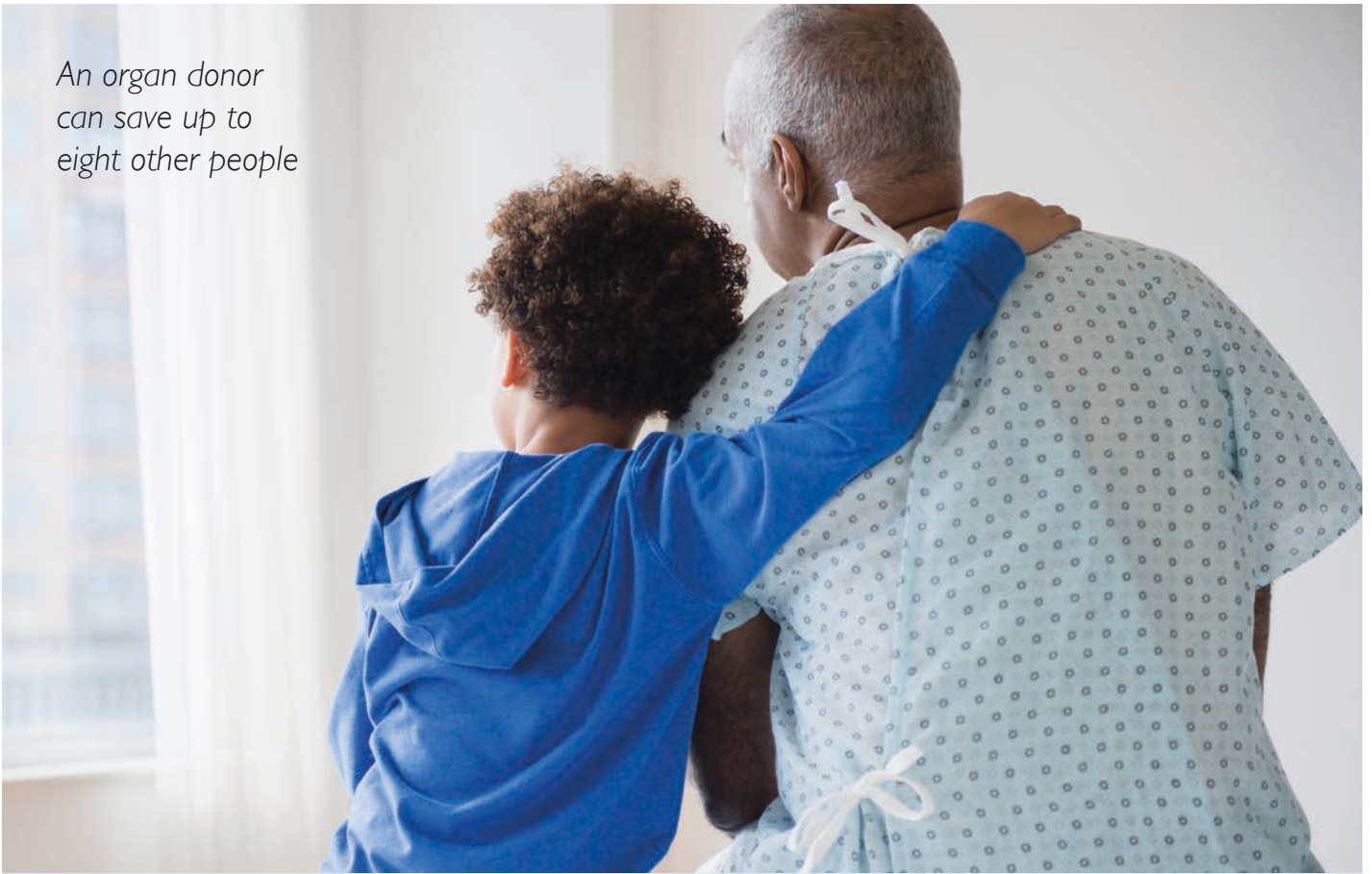
Another possibility that more and more clinics are investigating is whether methods can be found to make use of organs that previously were rejected as it was considered that their function was too poor and in the event of a transplantation would risk making the recipient even more ill. Organs considered as marginal may come from older donors, infected donors (such as hepatitis B & C and HIV) or donors with a high BMI, diabetes or high blood pressure. The introduction of marginal organs in the donation process has meant that the decision to accept an organ or not has become more complex than previously. However, for most patients waiting for an organ, the benefits of a marginal organ outweigh the risks

## DISTRIBUTION OF LUNG TRANSPLANTATIONS CARRIED OUT 2013-2017

Source: GODT, OPTN and the company's own analyses



*An organ donor  
can save up to  
eight other people*



## Sweden needs to be better at organ donation

Every week someone in Sweden dies quite unnecessarily while they wait for a new organ. For several years MOD – More Organ Donation – has dedicated itself to reducing transplantation queues and to more people saying YES to donating their organs.

### **What are MOD's objectives?**

– More Organ Donation is working so that no-one in Sweden has to die while waiting for an organ. This is a long-term objective that requires many forms of change and it also requires cooperation at many different levels.

### **Why is there a shortage of donated organs in Sweden?**

– At present we have a system failure in Sweden with regard to how we work with organ donation. We have the greatest will in the world – nine out of ten people say that they want to donate their organs. At the same time an incredibly small number of people get the opportunity to actually become

donors. Of the almost 100,000 people who died in 2018, only 182 were able to donate their organs after their death. MOD is working so that people who wish to donate their organs get the opportunity to do so. Using established practice from other countries and changing legislation we could double the number of donors in Sweden. It would save tax revenue, relieve the pressure on the health service and at the same time save lives.

### **How do you work to achieve your objectives?**

We share XVIVO Perfusion's vision that no-one should need to die while waiting for an organ. To achieve this vision

we have identified a number of areas to focus on. By talking about the organ donation issue in a personal and emotional way, we have created new insights and got thousands of people to care and come to a decision on the issue.

**MOD was founded in 2012 and is a voluntary association that works so that no-one needs to die while waiting for an organ. At [www.merorgandonation.se](http://www.merorgandonation.se) you can read more about MOD and about how you can support their work.**

**MOD**  
merorgandonation

# TRANSPLANTATION

## – A TURNING POINT IN LIFE

An estimated 250,000 patients or more are at present waiting for a new organ in the US and Europe. Most people are waiting for a kidney, many for a liver and some for new lungs or a heart. The reason for their condition can be congenital and maybe hereditary, but it can also be due to exposure to tobacco, alcohol or infection. Everyone has one thing in common, however – they are very seriously ill and have a life expectancy that is highly limited if they do not receive a new organ. Approximately 25% of patients waiting for new lungs or a new heart die while waiting for a new organ or are removed from the waiting list as they become too ill to undergo a transplantation.

### Lung transplantation

Lung transplantation is the last alternative to treat a patient with terminal lung disease, where other medical or surgical alternatives are exhausted and the expected life expectancy is less than 2 years. The diseases behind a patient needing new lungs are primarily chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF), idiopathic pulmonary fibrosis (IPF) and pulmonary arterial hypertension. The World Health Organization (WHO) estimates that there are 200 million people suffering from COPD and the disease causes 3 million deaths per year, which makes it the third most frequent cause of death. Common causes of COPD are smoking tobacco and exposure to different forms of pollution. Cystic fibrosis is a hereditary disease that causes the abnormal formation of mucus which primarily impacts the lungs and the digestive organs. The sticky mucus in the airways is difficult to cough up and leads to repeated infections. Idiopathic lung fibrosis is a disease that causes scar tissue to form in the lungs, which reduces lung volume. Pulmonary arterial hypertension means that the pressure in the blood vessels of the lung is too high, which is due to the fact that the lungs' blood vessels have become too narrow.

The first lung transplantation was performed in 1963, but it was not until 1982 that the first patient with a lung transplant lived

long enough to leave hospital. Life expectancy after a lung transplantation has increased as surgical techniques have been refined, immunosuppressive drugs have been introduced, post-operative care has improved and preservation solutions and technologies have become more advanced. Today lung transplantation is an established standard treatment for patients with terminal lung disease. Transplantation consists of a lung, both lungs, part of a lung (lobe) or in rare cases as a combination of lungs and a heart. The survival rate after a lung transplant is relatively good – 80% after the first year – but in spite of this lung transplantations are performed to a limited extent. The main reason for this is a shortage of organ donors, but another limitation is that the lungs are often impacted by rapidly impaired function when the donor dies and in four out of five cases the lungs are in too poor a condition to be able to be transplanted.

As lung transplantation is a complicated procedure that is a matter of life or death for the patient, surgeons reject lungs when they are uncertain about their quality. This assessment is often subjective and must be made under great time pressure.

Living with a terminal lung disease involves greatly reduced quality of life and has a great impact on the patient's daily life. If the availability of donated organs were greater, more patients with terminal lung disease would be able to receive a transplant and thus be given the opportunity of a longer and better life.



*Beatrice Hallby  
lives with cystic  
fibrosis and has  
a lung transplant*

### **Can you tell us about your disease, cystic fibrosis (CF)?**

I was born in 1994 with ileus, which is an early sign of the hereditary, chronic disease cystic fibrosis (CF). CF affects the salt balance in the body and results in the mucus produced being abnormally thick and sticky. As the years go by the mucus will block the alveoli where gas exchange takes place and the lungs die bit by bit. To stay as healthy as possible intensive treatment is necessary, with expectorants and mucolytics, as well as physical activity.

### **When and how did a lung transplant come up?**

I lived my life like anyone else until I was 21, when my lungs began to deteriorate and it was not long before my doctor asked how I felt about a lung transplant.

A lung transplant did not sound particularly enticing, but I didn't have the time or the desire to die, so I chose the

least negative alternative.

I underwent a transplantation assessment where they found that I was ill enough to need new lungs, but well enough to be able to undergo a lung transplantation. In August 2017 I was put on the famous waiting list for new lungs.

The waiting meant that I lived in a vacuum. Winter came and went, the first day of spring arrived, and no new lungs turned up. The summer of 2018 was the hottest and best summer I have ever experienced. My one-year anniversary on the waiting list came and I started to get tired. But then one night in August the telephone call came. My new lungs had arrived.

### **How were the operation and the time after the operation?**

The operation went smoothly and quickly and I made fast progress while I was in thorax intensive care. When

I came to the ward I began to climb the walls pretty quickly. I wanted to go home to my new life and carry on where I had left off that night in August. Almost exactly six months have now passed since the operation. It has not always been easy, sometimes I have been on the verge of giving up – difficult. I have managed to have treatment against rejection of the transplant, but I have also started to exercise and have taken up my riding again.

I literally breathe organ donation thanks to someone having said YES to donating their organs after their death. So it is my duty to live for us both. Live Life – Pass it On.

– Beatrice Hallby

**Cold preservation – traditional method for preserving donated lungs**

The traditional method for taking care of and preserving donated lungs cools down the lungs to reduce the metabolism. This is done by rinsing the lung's major blood vessels with a cold perfusion solution which not only reduces the temperature but also rinses away blood from the donor, which contains factors and substances that are detrimental to the lungs. The lungs are then kept refrigerated while they are transported to the recipient hospital and up until transplantation. Cold preservation is standard treatment for donated lungs and is carried out using Perfadex®/Perfadex® Plus in 90% of all cases. When kept cool, lungs can be preserved for six to ten hours outside the body and be successfully transplanted.

Cold preservation is an established and safe method for preserving donor lungs outside the body, but does not contribute to increasing the availability of transplantable organs. A limitation of cold preservation is that it does not allow evaluation of the donated lungs, as this cannot be done in a refrigerated condition.

**Warm perfusion – Ex Vivo Lung Perfusion (EVLP) – the STEEN Solution™ method**

In collaboration with Professor Stig Steen at Lund University, XVIVO Perfusion has developed a technology and solution for warm perfusion of lungs, with the aim of making more organs available for transplantation. The method is called Ex Vivo Lung Perfusion (EVLP) and involves warming up the donated lungs to body temperature and perfusing them with a special perfusion solution – STEEN Solution™. During the process the lung is connected to a pump for circulation and to a ventilator to simulate breathing. EVLP recreates a favorable environment like that in the body (in vivo), which gives the lungs and their cells a healthy stable environment outside the body. Furthermore, the method

enables evaluation of the lungs' function outside the body by observing flows, pressure and gas exchange. The transplantation team is thus given a method to objectively assess the lung before the definitive decision concerning transplantation is taken. It is also possible to X-ray the lungs outside the body, inspect them in a bronchoscope and suction secretions from the airways.

Most people agree that the greatest potential for increasing the number and quality of organs lies with the methods for perfusion, preservation and reconditioning of organs, and lungs are no exception. In clinical use in the US, Europe and Canada, it has been seen that lungs that have initially been assessed to be non-transplantable have been able to be transplanted after they have successfully undergone STEEN Solution™ perfusion. This has been demonstrated in both marginal DBD lungs and DCD lungs.

As the lungs are given the opportunity to recover and their function can be evaluated outside the body, a larger proportion of donated lungs can be used.

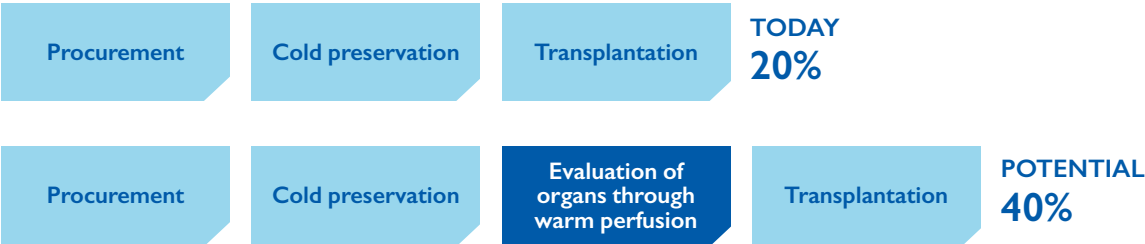
With today's standard method a lung can be preserved outside the body for 6-10 hours. In the USA FDA have approved up to 5 hours of EVLP, but this restriction does not apply in the rest of the world. It has been clinically demonstrated that the STEEN Solution™ method can extend the time the lung can be preserved outside the body. Cases with preservation times up to 24-hours have been demonstrated in clinics. Clinics thus have a better chance to find the right recipient and to plan and make their work more efficient.

To facilitate and standardize use of STEEN Solution™, XVIVO Perfusion has developed a machine for warm perfusion of the lungs, the XPST™ (XVIVO Perfusion System).

**MORE LUNGS AVAILABLE WITH WARM PERFUSION**

Today approximately 20% of all donated DBD lungs can be used. Use of warm perfusion enables use of approximately 40% of all donated DBD and DCD lungs, including marginal lungs

DBD: Donation after Brain Death    DCD: Donation after Circulatory (or Cardiac) Death



\* Marginal lungs = lungs that were initially considered to be not possible to transplant.



### XPS™

With its integrated Hamilton ventilator and MAQUET CardioHelp centrifugal pump, the XPS™ is the most flexible and complete platform on the market for EVLP and gives the transplantation team full control of the whole process. Its design means that X-rays can be taken and automatic measurement of weight, oxygen, carbon dioxide and pH can be carried out during the ongoing EVLP evaluation. The XPS™ has a user-friendly graphic interface with touchscreen functionality and data recording of the lung's values during the entire EVLP procedure, which provides data for analysis and evaluation before a final decision on whether to use the lung.



### PERFADEx® PLUS

Perfadex® Plus is an improved, ready-to-use version of Perfadex® that simplifies use and increases safety. Perfadex® Plus is a solution intended to rinse the blood vessels and refrigerate donated lungs outside the body until transplantation takes place. Perfadex® Plus is considered to be the gold standard for cold preservation of lungs and has been used in more than 50,000 lung transplantations worldwide.



### STEEN SOLUTION™

STEEN Solution™ is a unique patented perfusion solution which is used to evaluate donor lungs in connection with transplantation. EVLP with STEEN Solution™ is a clinically applicable method where perfusion of STEEN Solution™ at normal body temperature makes it possible to preserve and assess the function of lungs outside the body before transplantation.



For the past several years I have had the great fortune to travel around the world sharing, teaching, and learning with other dedicated medical professionals how we can improve organ transplant outcomes and increase the number of people who receive lifesaving transplants. When we combine great minds and cutting-edge technology together, we can move to a point in medicine where no one must die waiting for an organ transplant. This is my passion, my motivation, my inspiration; every day to do my best, using the tools and support that XVIVO Perfusion provides me with to help others.

My professional satisfaction comes directly from helping others succeed. And when we can bring together and share knowledge from diverse cultures we can lift all of society regardless of demographic differences.

This past year I have been working alongside of my colleagues to bring together one of the most successful lung transplant programs in the world, The Cleveland Clinic, and one of the quickest developing lung transplant programs in the world, The Shanghai Pulmonary Hospital together for an opportunity to develop a clinical and research collaboration. I look forward to continuing to help new and

underserved regions around the world develop transplant programs that will improve the lives of their communities and eliminate deaths while waiting for an organ transplant.

I am proud and honoured to be a part of such an extraordinary team at XVIVO Perfusion that has such a vision.

Sincerely,  
Rodney Jones, Technical Advisor

Photo: Rodney Jones (middle), Technical Advisor at XVIVO Perfusion with Professor Jijang (left) and Professor Yuping (right) from Shanghai Pulmonary Hospital in Shanghai, China.

## Market size and growth

XVIVO Perfusion's customers are specialized transplantation clinics worldwide. A total of just over 200 clinics perform lung transplantations, of which approximately 70 are in North America and approximately 80 in Europe. There are 15 clinics that perform more than 50 lung transplantations per year, and the largest clinics in the world perform more than 150 transplantations per year. At the same time about half of the clinics perform fewer than ten transplantations per year.

Just over 6,000 lung transplantations are performed per year, and North America, which is the largest market in the world, accounts for almost half of the number of lung transplantations. The ten largest countries in the field of lung transplantation account for about 80 percent of the total number of lung transplantations. In Sweden around 60 transplantations are performed per year at the clinics in Lund and Gothenburg. In large parts of the world no lung transplantations are performed at all, due to a number of factors such as economic conditions, organ donation systems and ethical and cultural obstacles.

The sales value for XVIVO Perfusion of a transplantation performed using cold preservation and Perfadex® Plus is approximately SEK 15,000. Using the STEEN Solution™ method, which includes the use of Perfadex® and other single-use products, the value for XVIVO Perfusion increases to between SEK 70,000 and 180,000 per transplantation, depending on what equipment is used. The total cost of performing a lung transplantation is between one and three million Swedish kronor.

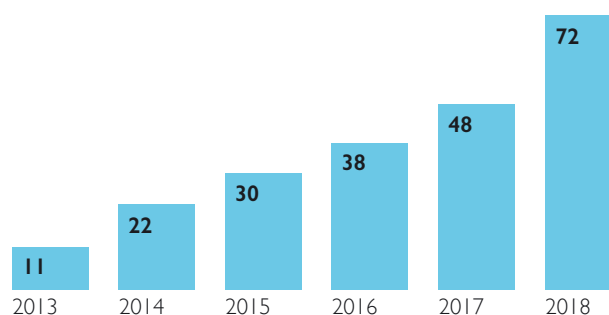
What decides the size and growth of the market is not the number of patients on the waiting list for an organ, but how many organs there are available for transplantation.

Market growth in terms of the number of lung transplantations is estimated to be approximately 7%, with greater growth in North America and Asia than in Europe. In the US growth is primarily driven by the increased number of organs used from heart-dead

donors, but also by the fact that so-called marginal organs are used to a greater and greater extent, that is organs that do not meet standard criteria for acceptance. In Asia growth is driven by increased knowledge of organ donation, both among the general public and in healthcare services, at the same time as there has been a change of attitude, above all among the younger generation. Many of the countries have built up a larger and more efficient infrastructure for organ donation and transplantation, and acceptance of the concept of brain dead has become more widespread.

There is at present primarily one competing product to Perfadex® for the indication of lung transplantation, namely Celsior from the French company Sanofi Aventis/Genzyme with an estimated market share of approximately five percent. In addition, there are locally produced competitors in China and Japan, for example. STEEN Solution™, the XPS™ and the accompanying single-use articles are the only medical technology products to have been approved by the FDA for ExVivo Lung Perfusion (EVLV) at body temperature of initially non-accepted donated lungs. The American company Transmedics has a perfusion machine with an accompanying solution that has been approved for EVLP of normal lungs during transportation.

## WARM PERFUSION SALES EXCLUDING NON-DURABLE GOODS\*, SEK MILLIONS



\* Warm perfusion sales excluding non-durable goods are sales of STEEN Solution™ and other sterile input goods used in each lung evaluation



Christer de Flon, manager responsible for sales in Asia.

## CHINA

There has been a considerable restructuring of the organ donation system in China since 2015, which has resulted in there today being more than 300,000 registered organ donors, according to the China Organ Transplant Development Foundation. This is also reflected in a significant increase in the number of transplantations performed – more than 16,000 during 2016. It is estimated that there are 300,000 patients in China who are in need of a new organ, but only 30,000 have been put on the waiting list. Between 2015 and 2017 the number of lung transplantations doubled to approximately 300, which places China among the 10 largest markets in the world. XVIVO Perfusion is represented in China by a distributor who is well-established in the field of transplantation and we expect strong expansion in the Chinese market.

## Heart transplantation

The first heart transplantation was carried out in 1967, but it was not until the 1980s that heart transplantation became established as a method. In Sweden the first heart transplantation was carried out in 1984, in Gothenburg. Heart transplantation is the last alternative to treat a patient with severe heart failure, where all other medical and surgical treatment alternatives have been exhausted. The most common causes of heart failure are that parts of the heart muscles have been weakened by one or more heart attacks, congenital heart defects (usually a univentricular heart), severe heart muscle disease, very high blood pressure and certain metabolic diseases.

### The market

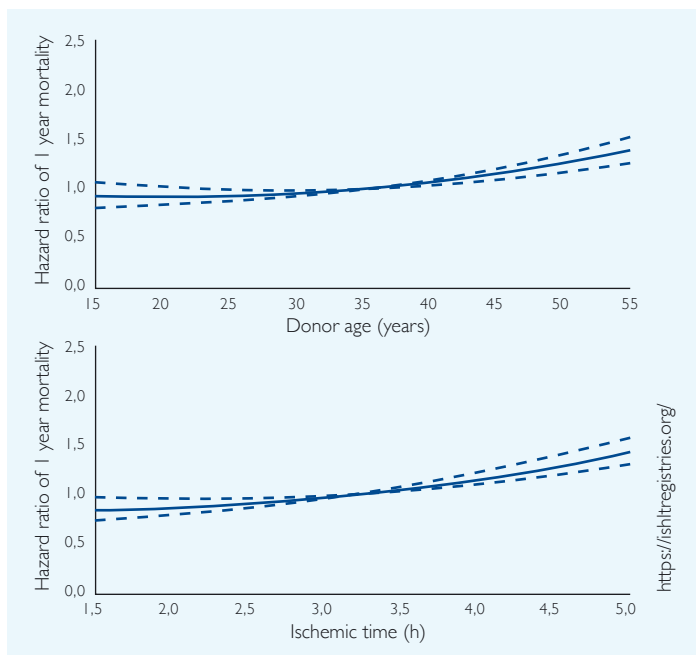
There are more than 350 specialized clinics in the world that carry out heart transplantations and approximately 7,500 heart transplantations are carried out per year. North America, which is the largest market in the world, accounts for almost half of the number of heart transplantations.

### Cold preservation – traditional method for preserving donated hearts

The standard method for preserving donated hearts is to cool down the organ, as is done for lungs. Cold preservation of the heart is, however, a great challenge as the safe time for preserving a heart outside the body is limited to just 4 hours. The time outside the body is directly correlated to the survival of the recipient, a relationship that is even more pronounced if the donor is older

– then the time outside the body should not exceed 2 hours. The time factor means that the distance that a heart can be transported is limited and reduces the chance of finding the most suitable recipient. This time limit is costly and results in difficult logistic issues, which leads to the loss of transportable organs, as they cannot be transported in the prescribed time frame.

When analyzing ISHLT's\* statistics regarding survival after a transplantation, it can be seen that the optimal donor is under 35 and that an ischemic time (the time without oxygen outside the body)



\*ISHLT: International Society for Heart and Lung Transplantation



of more than 3-3.5 hours involves a greater risk for the recipient. With a method that allows a longer preservation time outside the body pending transplantation, more hearts could be transplanted, at the same time as there would be savings regarding logistic and transplantation costs.

### **New method for heart preservation during transportation – Non Ischemic Heart Preservation (NIHP)**

In collaboration with Igelösa Life Science and Professor Stig Steen, XVIVO Perfusion has developed a new method for preserving and transporting a heart from a donor in an optimized manner; by means of non-ischemic heart preservation. The new preservation method includes a machine that supplies the heart with important substances in an oxygenated solution before transportation. If the new method proves to work as well in humans as in animals, it will be possible to use considerably more hearts for transportation. A longer preservation time means that there are better opportunities to find the most suitable recipient, and distance becomes less of a limiting factor.

The first clinical heart transplantation using the new technology was successfully carried out in 2017 at Skåne University Hospital in Lund. The new method increases the time a heart can be preserved outside the body (ex vivo) from today's four hours to up to approximately 12 hours, which significantly extends the time window when a heart transplantation is possible.

There are two American competitors in the field of machine perfusion of donated hearts, Transmedics OCS and Paragonix SherpaPak.

## **PATENTS AND TRADEMARKS**

XVIVO Perfusion invests a great deal in research and development. Patent protection is thus important in XVIVO Perfusion's business, as the product cycles are long and considerable investments are made in the development of products. XVIVO Perfusion thus applies for patents that will protect existing and future products. Applications are submitted continually and at present XVIVO Perfusion has 17 families of patents or patent applications at different stages.

STEEN Solution™ is protected by patents in 15 countries, including EP validations. These STEEN Solution™ patents are valid up until 2021/2022 and protect both the product and the use of STEEN Solution™.

PrimECC®, which is XVIVO Perfusion's solution for use in heart-lung machines, is currently protected by patents in 15 countries, including EP validations. These patents are valid up until 2031. The American patent protects the use of a solution similar to PrimECC for use in the priming of a heart-lung machine. Its European equivalent protects the product PrimECC®.



Non Ischemic Heart Preservation (NIHP) - a new method which provides optimum conditions by providing the heart with important substances in an oxygenated solution directly after the organ procurement to avoid ischemic time, but at the same time use the benefits of cold preservation (low metabolic activity, resting state).

# FROM RESEARCH TO SALES

## Produktutveckling Product development

XVIVO Perfusion primarily conducts product development in-house, while research is mainly carried out in collaboration with world-leading institutions and researchers in all large markets in the world. Since the end of the 1990s the company has had close collaboration with leading people in the field of lung transplantation, amongst others Professor Stig Steen in Lund and Doctor Shaf Keshavjee in Toronto.

In order to standardize and facilitate the use of STEEN Solution™ the company has developed a machine for lung perfusion called XPS™ (XVIVO Perfusion System). Since 2016 the XVIVO LS™ system has also been a part of XVIVO Perfusion's product portfolio. Both the XPS™ and the XVIVO LS™ systems simplify the EVLP (Ex Vivo Lung Perfusion) process, shorten the start-up time and use fewer human resources than a manual EVLP system. The XPS™ is a complete system that also enables X-rays of the lung and automatic measurement of oxygen and PH during the ongoing evaluation of the lung.

XVIVO Perfusion owns all rights to the products that the company markets, including the XPS™, XVIVO LS™, Perfadex® Plus and STEEN Solution™.

## Clinical studies

Clinical studies are of great strategic importance in the field of transplantation. Study data for the XPS™ and STEEN Solution™ have been important both as a basis for obtaining product approval worldwide and continue to be important in the work of expanding the indication so that more lungs can be used for transplantation. Most of the studies on STEEN Solution™ have been carried out since 2010 and the conclusion from these studies is that patients who have received suboptimal lungs according to the assessment of the lungs from the donor in vitro, but which after treatment with STEEN Solution™ were assessed to be acceptable, had similar results to those patients who had received a transplant consisting of optimal lungs. It is first and foremost the clinic in Toronto, which is the clinic that has performed the most transplantations in the world using the STEEN Solution™ treatment, that has confirmed these excellent results in later follow-up of patients for up to five years after transplantation.

XVIVO Perfusion's largest study ever; the NOVEL/NOVEL Extension study in the US, was designed to safely increase the number of usable lungs from the donor pool in the US. The study compared the clinical results after transplantation of lungs that had undergone warm perfusion after having been initially assessed as unusable with a control group of lungs that had initially been assessed as usable.

## THE ADVANTAGES OF THE STEEN SOLUTION™ METHOD

PROBLEM	STEEN SOLUTION™	ADVANTAGE
<ul style="list-style-type: none"><li>&gt; 70% of sampled organs are not used due to that it is not possible to test lung function outside the body</li></ul>	<ul style="list-style-type: none"><li>Functional testing, organ perfusion outside of the body, a possible, reconditioning effect</li></ul>	<ul style="list-style-type: none"><li>More of the donated organs can be used</li></ul>
<ul style="list-style-type: none"><li>Very limited potential donor group (brain dead) = few organs to transplant</li></ul>	<ul style="list-style-type: none"><li>Use of cardiac death donor enables a large number of potential donors</li></ul>	<ul style="list-style-type: none"><li>More organs available for transplantation</li></ul>
<ul style="list-style-type: none"><li>Limited time to match organs with recipients due to a maximum of 6–10 hours outside the body</li></ul>	<ul style="list-style-type: none"><li>Maximum time of approximately 24 hours outside the body gives a more time to match organs with recipients</li></ul>	<ul style="list-style-type: none"><li>More organs can be used</li></ul>
<ul style="list-style-type: none"><li>Emergency surgery (usually at night) due to maximum 6–10 hours outside the body</li></ul>	<ul style="list-style-type: none"><li>Maximum time of approximately 24 hours outside the body gives more time for planning a procedure</li></ul>	<ul style="list-style-type: none"><li>Operation during daytime, less burden on health care, longer transport of organs and recipients possible</li></ul>
<ul style="list-style-type: none"><li>High total cost for emergency surgery due to maximum 6–10 hours outside the body</li></ul>	<ul style="list-style-type: none"><li>Maximum time of approximately 24 hours outside the body gives more time for planning a procedure</li></ul>	<ul style="list-style-type: none"><li>Lower total cost due to better opportunity for healthcare planning, lower transport costs</li></ul>
<ul style="list-style-type: none"><li>Patients die on transplant waiting list due to lack of organs</li></ul>	<ul style="list-style-type: none"><li>More patients can receive new lungs</li></ul>	<ul style="list-style-type: none"><li>More patients on the waiting list are given the opportunity of transplantation</li></ul>

The first part of the study was ongoing in the US between 2012 and 2014 and formed the basis of the application for HDE approval in the US. In 2014 FDA's expert panel voted unanimously that the XPS™ with STEEN Solution™ meets the requirements for HDE approval and then the FDA made the final decision concerning regulatory approval of the products. This approval is the first in the US for warm perfusion of an organ. The NOVEL study has subsequently continued and during 2017 all 220 patients were included in the study. During 2018 XVIVO's application for PMA (Pre-Market Approval) was submitted.

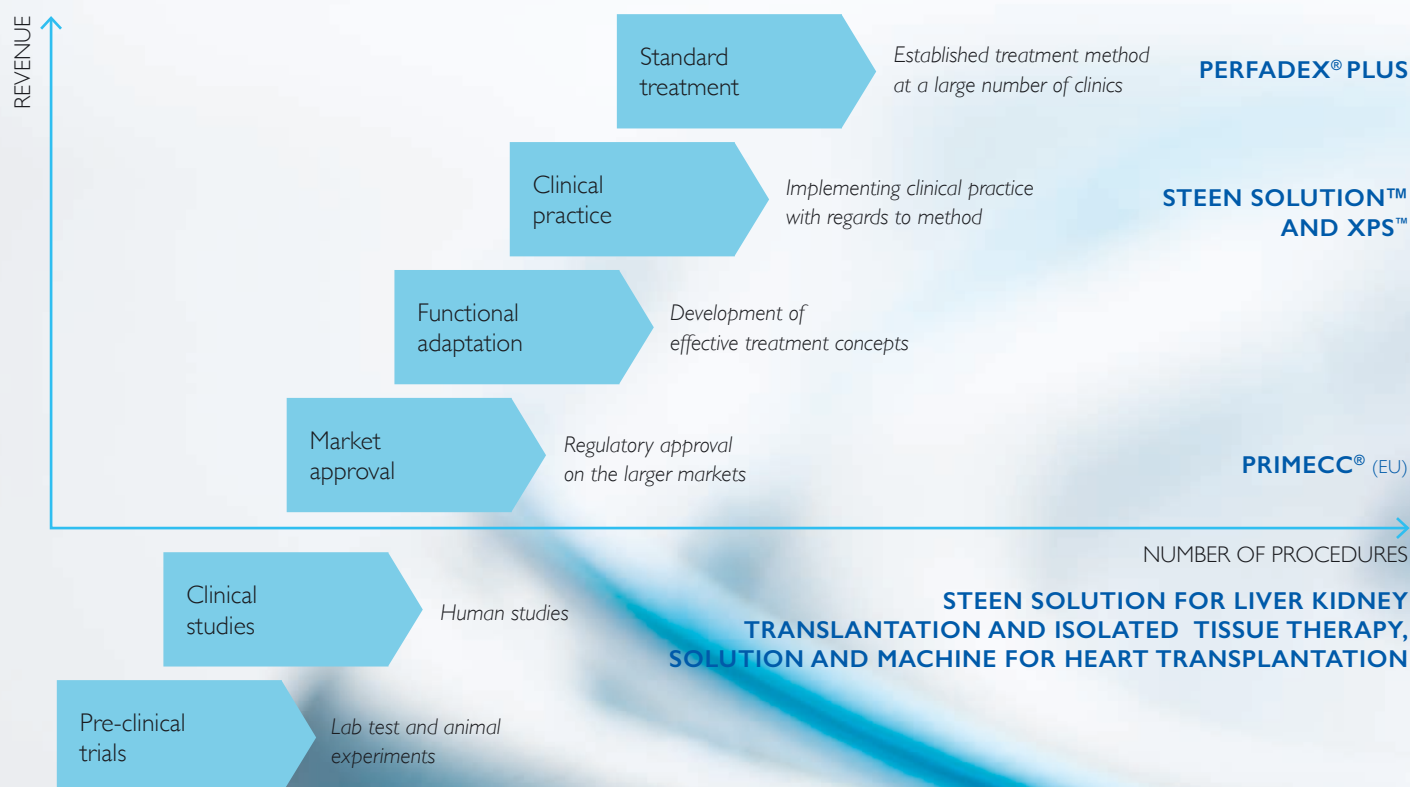
In 2015 a clinical study was started using STEEN Solution™ for liver transplantation in Toronto, Canada. The liver was perfused using STEEN Solution™ in normothermic conditions. STEEN Solution™ was originally developed for warm perfusion and evaluation of lungs but with certain additives can be used for perfusion of the liver. The modified STEEN Solution™ means that the liver can be subjected to warm perfusion and evaluated. The first clinical study on STEEN Solution™ in the liver demonstrates

that the product is safe to use in livers and that livers can be evaluated using warm perfusion with STEEN Solution™.

Recruitment for the the PrimECC® study, which was carried out at Sahlgrenska University Hospital, was completed in 2017. The study comprised 80 (40+40) patients randomized to heart-lung machines which had been primed with either PrimEEC or with the conventional, simpler solution that is used at the hospital today. Analysis of the results, which was published in a press release during the second quarter of 2018, shows that the product is safe as well as interesting findings regarding reduced adverse effects when using PrimECC®.

Several hundreds of thousands of heart operations are carried out worldwide each year with the use of a heart-lung machine. The blind, randomized study carried out using PrimECC® at Sahlgrenska University Hospital shows, as expected, that patients have a better fluid balance during and after the operation if the heart-lung machine has been primed with PrimECC®. Moreover,

## VALUE CHAIN FROM EARLY DEVELOPMENT TO STANDARD TREATMENT



the results verify that PrimECC® is a safe product to use. The company has decided to continue to perform clinical studies so as to expand documentation of clinical use of PrimECC® and to spread use of PrimECC®.

### Product approval

Perfadex®, the XPS™ and STEEN Solution™ are today approved for sales in all major markets in the world. The XPS LS™ is currently approved for sales in Europe, Canada and Australia. XVIVO's products are classified as medical devices in all countries where product approval has been obtained.

XVIVO Perfusion has had HDE approval of STEEN Solution™ since August 2014 for use together with the XPS™. HDE approval means that the U.S. Food and Drug Administration (FDA) has approved the products after studies on only a limited number of patients. HDE approval may be granted if there is no comparable product on the market for treatment of the indication in question and if it is an indication with a limited number of patients.

In addition to the products that XVIVO Perfusion markets for organ transplantation, one product, PrimECC®, has been developed for priming of heart and lung machines. PrimECC® has obtained CE marking and XVIVO Perfusion has been granted a patent for PrimECC® in the US, the EU, China and Japan. During 2018, the company strengthened quality and regulatory expertise to enable approval of new products in the main markets.

### Marketing and sales

#### Sales organization

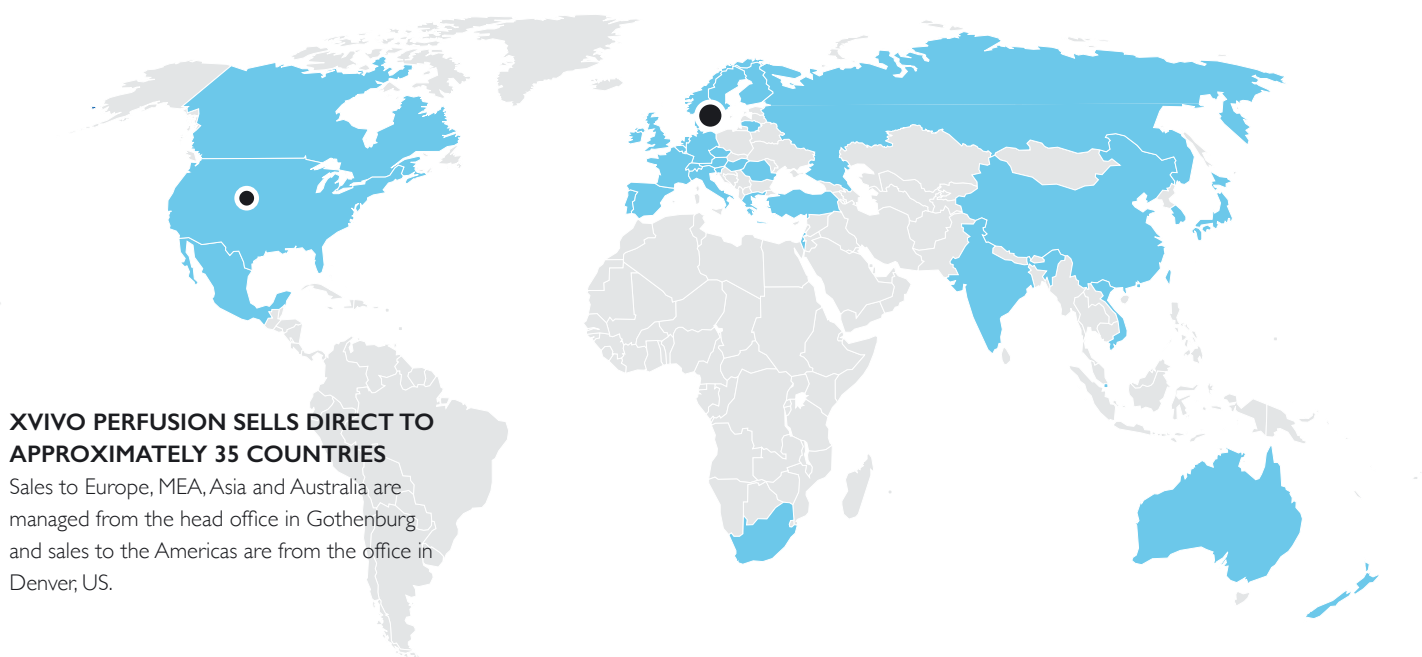
Perfadex® is sold to lung transplantation clinics worldwide and STEEN Solution™ is used clinically today in most countries

that perform lung transplantations. XVIVO Perfusion's product portfolio is today marketed by the company's own sales organization in Europe and North America and is mainly distributed direct from Gothenburg and Denver. In markets outside North America, Europe and the Asia/Pacific region the company primarily uses distributors.

There are just over 200 transplantation clinics in the world, which makes it possible to reach a large part of the market with a relatively limited organization. Since 2012 XVIVO Perfusion has invested in building up a strong commercial platform in North America and Europe through its own sales organization. Through direct contact with our customers we create a strong relationship and ensure that they receive the right equipment, training and support. During 2018 XVIVO Perfusion expanded the commercial organization to further accelerate market penetration. In Europe and the US we have added field-based personnel in the technical support function in order to strengthen support for the clinics. Furthermore, we have expanded our distribution network, above all in Asia.

#### Cooperation with leading clinics

It is a requirement that the products have regulatory approval and clinical studies are thus performed to document product and patient safety. However, good sales growth requires a high degree of acceptance from leading clinics. It is of the greatest importance to continually be at the leading edge of development in the area of lung transplantation and develop the clinical use of STEEN Solution™. XVIVO Perfusion runs many research projects of different kinds together with partners in the US, Canada and EMEA. This is a way of maintaining the level of competence in the clinical area and ensuring that the company will also be at the leading edge of clinical development in the future.



#### XVIVO PERFUSION SELLS DIRECT TO APPROXIMATELY 35 COUNTRIES

Sales to Europe, MEA, Asia and Australia are managed from the head office in Gothenburg and sales to the Americas are from the office in Denver, US.

In close collaboration with the company, the customer contributes important knowledge and experience in order to internally drive the process forward at each center. XVIVO Perfusion includes the customer's experience in all market processing and product development.

### Training program

Lung transplantation is a complex treatment that requires great expertise from several target groups with great experience in each area. XVIVO Perfusion should be an attractive partner for our clinics as regards competence development and develops high-quality training programs. This work was expanded during 2018. Increasing clinics' knowledge through hands-on training is an important part of the company's strategy to drive competence development in the profession. Education and training have been carried out locally by XVIVO Perfusion at several clinics, but also at the company's training facilities in Denver and Lund. Furthermore, we have on several occasions gathered together clinics for an exchange of their experiences and advanced training. Customers have shown great interest and received these initiatives well, which shows that XVIVO Perfusion offers a technology that is the future within the field of lung transplantation.

### Reimbursement

XVIVO Perfusion has worked on securing reimbursement for the EVLP process over a long period of time. In 2017 three reimbursement codes were received for the entire EVLP process in the US. These are so-called CPT codes and mean that as from January 1, 2018 hospitals in the US can receive reimbursement for the surgeon's and the team's time spent on an EVLP. The CPT codes also mean that the complicated reimbursement process for American hospitals has now been simplified.

### Organization

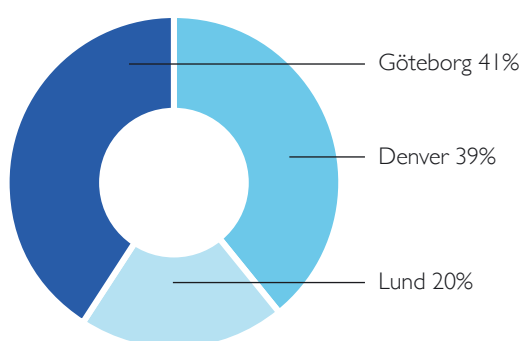
XVIVO Perfusion was set up as a company of its own in 2012 and began to build up its own organization, which today consists of just over 40 employees at the head office in Gothenburg and the subsidiaries in Denver and Lund. Joint functions such as QA/RA, Global Marketing and Global Finance are located in Gothenburg. In addition, the company has 10 or so consultants linked to the business. Each site acts as a Centre of Excellence – Gothenburg for solutions for the lungs and heart, Lund for production and development of heart machines and Denver for lung machines.

XVIVO Perfusion has three geographic market organizations, the Americas, EMEA/Africa/the Middle East and Asia/Pacific, and Asia. Gothenburg and Denver have the highest number of employees, and the majority work in research and development (36%) and sales and marketing (37%). 39% of the employees are women.

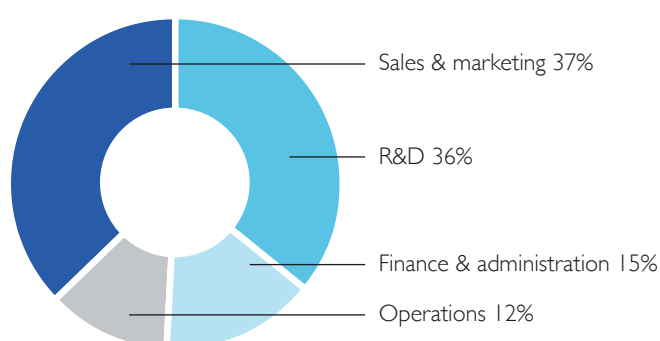
### MARKET STRATEGY

- Continued focus on established markets, increasing penetration of EVLP.
- Geographic expansion in markets outside Europe, North America and Asia/Pacific.
- Secure reimbursement for our products in all prioritized markets.
- Clinical studies to strengthen documentation and broaden the indication.

### EMPLOYEES PER COMPANY



### EMPLOYEES PER FUNCTION



# RESEARCH FOR NEW INDICATIONS

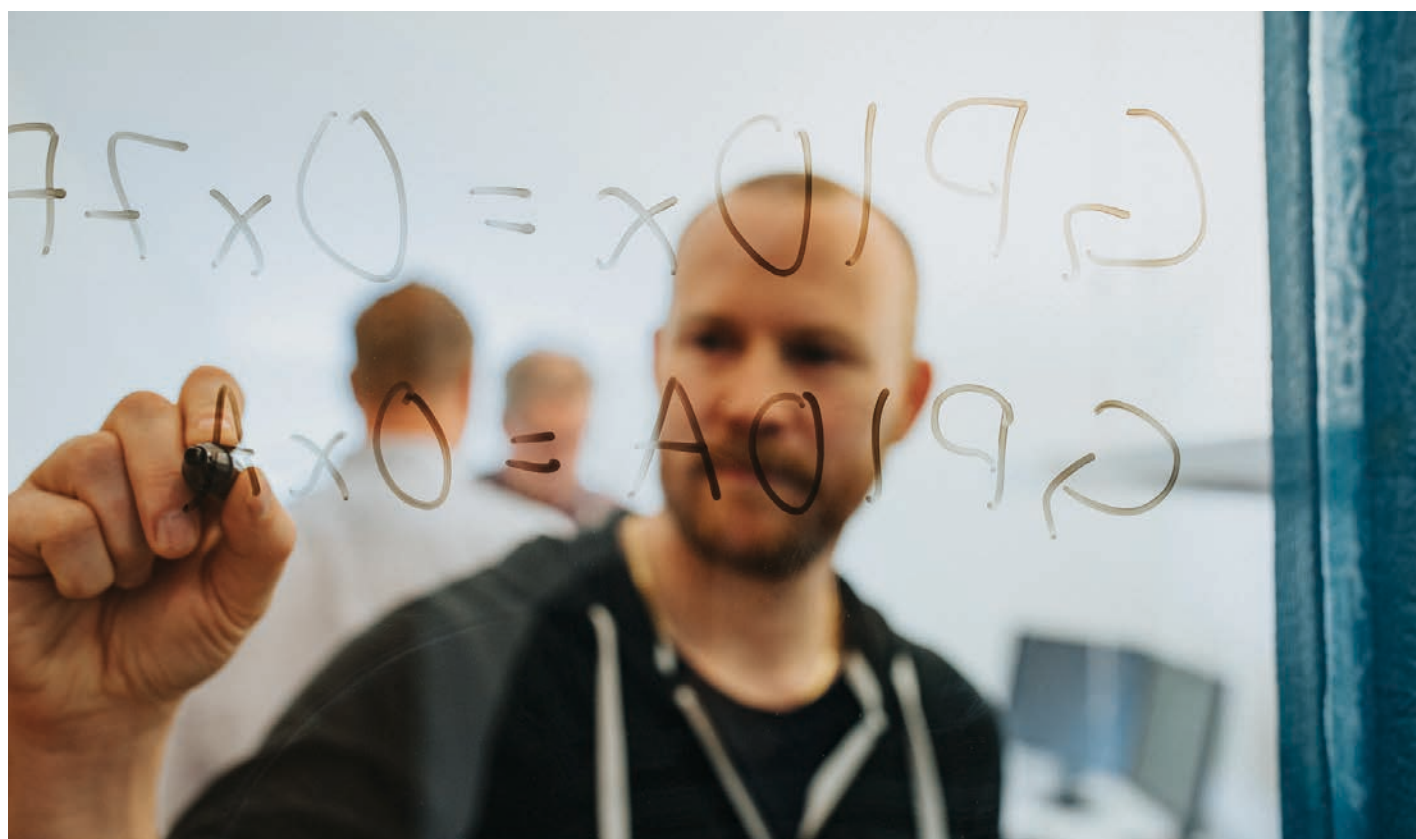
## Research and development strategy for new indications

XVIVO Perfusion's main strategy is to develop solutions and machines for perfusion of donated lungs and the heart before transplantation so that more donated organs are used for transplantation. Most of the company's resources are allocated to research into heart and lung transplantation. In addition to thoracic transplantation, the company is developing the use of STEEN Solution™ and similar solutions for new indications in areas where the company has state-of-the-art competence and experience. Examples of areas where the company is developing the use of STEEN Solution™ for new indications are:

- Warm perfusion using STEEN Solution™ in the transplantation of other organs than lungs, for example the liver and kidneys.
- Drug administration to isolated organs and tissues (isolated issue therapy) in order to be able to optimize dosages and reduce adverse effects – for example in in vivo treatment of metastatic cancer of the lung.

A current example of development of a product for new indications is PrimECC®, which is used for priming the heart-lung machine before open heart surgery. XVIVO Perfusion seeks to develop new indications such as this where there is great market potential and clear synergies with existing sales areas and where the company can take advantage of:

- the company's comprehensive experience of research and of taking projects from research and development, through the process of obtaining regulatory approval (in all major markets in the world, including the FDA in the US) and subsequently to various phases of establishment on the market,
- the company's established relationships with world-leading researchers and transplantation centers
- the company's global distribution and market presence.



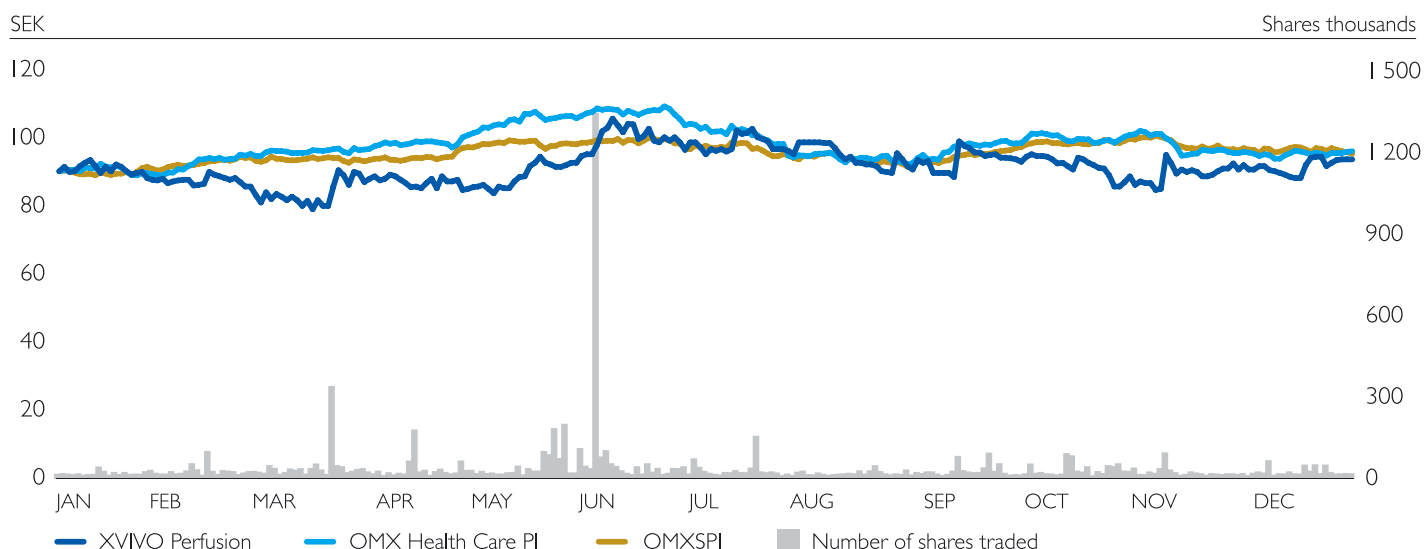
## CURRENT RESEARCH PROJECTS FOR NEW INDICATIONS

Table briefly describing XVIVO Perfusion's current research projects for new indications, what underlying market need they address and what stage they are at.

PROJECT	DESCRIPTION OF UNDERLYING MARKET NEED	STATUS
<b>Machine and solution for ex vivo preservation of the heart before transplantation.</b>	The demand for heart transplants is currently much greater than supply due to a shortage of transplantable hearts. At the same time the percentage of hearts used is only approximately 30% (US). XVIVO Perfusion is thus collaborating with Professor Stig Steen and Igelösa Life Science to develop the next generation of heart preservation products for transplantation. The products consist of both circulation apparatus and fluid that will contribute to better preserving the heart outside the body and thus contribute to more heart transplants being performed and more patients being given a last chance of a longer life and a better quality of life.	The products are in the clinical studies phase. The company is working to begin clinical studies and an application has been submitted to the Swedish Medical Products Agency. These studies will form the basis of the application for regulatory approval of the products.
<b>PRIMECC®</b>	PrimECC® is a fluid developed in collaboration with Professor Stig Steen in Lund to prime heart-lung machines used to drive blood circulation and take over oxygenation of the blood instead of the heart and lungs during heart operations. PrimECC® serves to avoid air bubbles coming into the patient's circulation when the heart-lung machine is started and to compensate for the blood volume that is outside the patient during the operation in the heart-lung machine. Today simple saline solutions are as a rule used for this purpose. It is hoped that the use of PrimECC® will reduce adverse effects related to the use of heart-lung machines. Several hundred thousand operations are performed each year using a heart-lung machine.	A proof of concept study performed using PrimECC® demonstrates interesting clinical results. In order to increase the documentation, the company carried out a randomized clinical safety study in 2016 and 2017 on 80 patients at Sahlgrenska University Hospital in Gothenburg. The results of the study showed that the product is safe and displayed positive clinical results. XVIVO Perfusion has patents for PrimECC® in the important markets of the US, the EU, China and Japan. PrimECC® has a CE mark and may thus be sold in Europe. The company is holding back on launch of the product until the result of the up-coming multicenter study has been analyzed.
<b>STEEN Solution™ for ex vivo warm perfusion of the liver before transplantation</b>	The demand for liver transplants is currently far greater than supply due to a shortage of transplantable livers. XVIVO Perfusion is trying to apply STEEN Solution™ in this area to contribute to increasing the number of liver transplantations that can be carried out so that more patients can be given a last chance of a longer life and a better quality of life.	In the clinical studies stage and the first liver transplant using STEEN Solution™ was performed in 2015 in Toronto, Canada. The focus is on initiating studies on STEEN Solution™ for transplantation of marginal livers.
<b>STEEN Solution™ for isolated tissue therapy for cancer treatment</b>	Adverse effects from cancer drugs are often severe and in certain cases high doses are lethal. If oncologists can isolate the organ to be treated, adverse effects can be reduced and more treatments can be carried out. XVIVO Perfusion is investigating the possibility of using STEEN Solution™ as a carrier of cancer drugs (cytostatics), initially in the treatment of cancers that have spread to the lungs.	In the clinical studies phase and the first administration of a drug to an isolated lung using STEEN Solution™ was carried out in 2016 in Toronto, Canada.

# THE SHARE

## DEVELOPMENT OF SHARE PRICE DURING THE YEAR



XVIVO Perfusion's share is listed on Nasdaq Stockholm under the ticker XVIVO, where it has been listed since November 28, 2016. The share had previously been listed on Nasdaq First North since October 8, 2012. A round lot comprises 1 share.

### Share structure

The share capital of XVIVO Perfusion AB (publ) amounted to SEK 674,815 at December 31, 2018, divided among 26,402,496 shares. Shares are traded on Nasdaq Stockholm, Mid Cap. All shares carry the same number of votes per share and entitle shareholders to an equal share of XVIVO Perfusion's assets and results.

### Development of the share price and turnover

The last price paid at December 31, 2018 for XVIVO Perfusion shares was SEK 132.00, which means an increase of 40 percent compared with the closing price at December 31, 2017. The OMX Health Care index rose by 20 percent and OMX Stockholm's index decreased by -8 percent in the same period. At the end of 2018 XVIVO Perfusion's market capitalization amounted to SEK 3,485 million based on the last price paid. The highest price paid during the period was SEK 169 on August 20. The lowest price paid during the period was SEK 82 on April 17.

The number of XVIVO Perfusion shares traded during the year amounted to 9,097,930 for a value of SEK 1.1 billion. The number of transactions was 36,415. The number of shares traded corresponds to 35 percent of the number of shares outstanding at the end of the year.

### SHARE PRICE INCREASE 2018

# +40%

### Dividend policy and dividend

XVIVO Perfusion's Board considers that the company should have a strong capital base to enable continued growth, both organic and through acquisitions. The Board and the CEO propose that no dividend be paid for 2018.

### Ongoing information

The XVIVO Perfusion share is listed on Nasdaq Stockholm, Mid Cap. Ongoing information about the company, such as press releases, interim reports and Annual Reports are to be found on the company website, [www.xvivoperfusion.com](http://www.xvivoperfusion.com).

### Insiders

XVIVO Perfusion is obliged to report to the Swedish Financial Supervisory Authority the names of persons who are insiders in the company. These people must register their shareholdings and any changes in their holdings. Board members and the CEO and CFO are considered to be insiders in XVIVO Perfusion. A complete list of insiders and their shareholdings and transactions is presented on the company's website, [www.xvivoperfusion.com](http://www.xvivoperfusion.com).

## Warrant programs

At the end of the year there were 477,000 warrants outstanding in two programs. The 2017 Annual General Meeting adopted a resolution to issue 243,000 warrants (2017/2019 series) with the accompanying right to subscribe for no more than 243,000 new shares for employees in the XVIVO Perfusion Group. Of these warrants, 198,000 had been subscribed for by employees and paid for up until December 31, 2018. The 2018 Annual General Meeting adopted a resolution to issue 315,000 warrants (2018/2020 series) with the accompanying right to subscribe for no more than 315,000 new shares for employees in the XVIVO Perfusion Group. Of these warrants, 279,000 had been subscribed for by employees and paid for up until December 31, 2018.

Warrant program 2017/2019 consists of 198,000 warrants and entitles warrant holders to subscribe for one new share at a share price of SEK 138.51 in May 2019. Warrant program 2018/2020 consists of 279,000 warrants and entitles warrant holders to subscribe for one new share at a share price of SEK 146.02 in May 2020.

If all warrants are utilized to subscribe for shares, the share capital will increase by approximately SEK 13,000 and the number of shares will increase by 558,000, corresponding to dilution of approximately 2.1 percent of the total number of shares and votes.

## Analyses

Pareto Securities, Danske Bank and RedEye regularly monitor XVIVO Perfusion.

## Ownership structure

According to Euroclear's official share register, XVIVO Perfusion had 5,137 shareholders at December 31, 2018. XVIVO Perfusion AB's (publ) ten largest shareholders at December 31, 2018 are reported below:

	Shares	Percent
Bure AB Equity	4 291 483	16,3
Swedbank Robur	1 630 000	6,2
Eccenovo AB	1 500 000	5,7
Fjärde AP fonden	1 250 000	4,7
Norron Fonder	1 249 590	4,7
Oppenheimer	1 000 000	3,8
Thomas Olausson	900 000	3,4
Handelsbanken Liv	557 367	2,1
Försäkringsaktiebolaget, Avanza Pension	478 386	1,8
Tredje AP fonden	461 236	1,7
Other shareholders	13 318 062	49,6
<b>Total</b>	<b>26 402 496</b>	<b>100,0</b>

Source: Euroclear Sweden's shareholder register at December 31, 2018.

## FINANCIAL REPORTS 2019

Interim report January-March 2019:  
Wednesday, April 24, 2019

Interim report January-June 2019:  
Friday, July 12, 2019

Interim report January-September 2019:  
Thursday, October 24, 2019

Year-end report 2019:  
Thursday, February 6, 2020

## INVESTOR RELATIONS

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*We empower  
transplant teams  
to save more lives*

# ADMINISTRATION REPORT

The Board of Directors and the CEO of XVIVO Perfusion AB (publ), corporate registration number 556561-0424, hereby submit the Annual Report and consolidated financial statements for the 2018 financial year.

## Business

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. Perfadex® and Perfadex®, two of the company's products, currently has a market share of about 90 percent in traditional cold preservation of lungs for transplantation. The company's products for warm perfusion, XPS™ and STEEN Solution™, are today the only products on the market that have market approval in the US for warm perfusion of marginal organs outside the body pending transplantation.

### Lung transplantation

A large problem in transplantation care is the lack of available lungs. Today approximately 20 percent of the donated organs available in the US are used, as the assessment is that it is far too risky to use the other donated lungs for transplantation. Using XVIVO Perfusion's product – STEEN Solution™ – the organ is cleansed of harmful substances from the donor, thus creating a better environment for the cells of the organ. The technology thus allows the organ to "recover" if possible and enables function tests to be performed outside the body. In clinical use in the US, Europe, Australia and Canada it has proved to be the case that many of the organs that were initially "refused" have been assessed to be usable after perfusion with STEEN Solution™ and have been used for transplantation in people with lung disease. The use of STEEN Solution™ therefore has the potential to increase the total number of lung transplants.

### Heart transplantation

Based on research done by Professor Steen and his research group, the Group's competence center for heart transplantation in Lund develops a portable machine and solutions for heart preservation. These products have been developed to increase the usability of donated hearts so that more heart transplants can be performed and more patients can be given a last chance to have a longer life and a better quality of life. Future focus is to carry out multi-center clinical studies as a basis for applications for regulatory approvals for the products in all major markets.

### Other indications

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

### Business concept

XVIVO Perfusion's business concept is to increase survival rates for patients requiring a transplant by providing effective products that increase the availability of organs that have the potential to survive after transplantation.

### Vision

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

## Objective

Bolagets mål är att etablera perfusion av organ med STEEN Solution™ och andra avancerade lösningar som standardbehandling vid organtransplantation so that more of these life-saving treatments can be implemented.

## Strategy

XVIVO Perfusion's strategy focuses on increasing the number of organs available for transplantation. By developing products for perfusion of organs and conducting clinical studies with these in all major markets in the world, XVIVO Perfusion shows that perfusion of organs provides more organs available for transplantation and thus more patients are given the chance of this life-saving treatment.

## Significant events

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 in the largest market of the world, the US. The NOVEL Extension Clinical trial, that completed enrollment of 220 (110 + 110) patients in 2017. 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 an HDE (Humanitarian Device Exemption). An HDE approval entails certain restrictions while a PMA approval does not entail any restrictions.

The PrimECC® study was completed during 2017 and was performed at Sahlgrenska University Hospital. The study included 80 (40 + 40) patients undergoing cardiac surgery, 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 shows that patients are given 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 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.

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.

8 XPS™ and XVIVO LS™ were delivered during 2018. At year end, 49 clinics had access to XPS™ or XVIVO LS™. The clinics are geographically distributed as follows. North America 27, Europe 18 and Asia and Pacific 4.

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.

### Development of the company's business

Since XVIVO Perfusion was established as an independent company through the spin-off from Vitrolife in October 2012, the company has established itself as the market leader in warm perfusion of organs prior to transplantation and has retained its position as market leader in cold preservation of lungs. During this period of a little more than six years, the company has built up market and research competence on both sides of the Atlantic and become the first and only company to have had a product for warm perfusion of a marginal organ approved in the US. During these six years, XVIVO Perfusion has increased sales by 228 percent (since 2012) to SEK 188 million with good gross and EBITDA margin. In addition, the company has, in the meantime, developed a product for priming or preparation of heart lung machines. This product is called PrimeCC® and is patented, CE-marked (approved for sale in Europe) and clinically documented in 40 patients in a safety study.

### GROUP'S KEY RATIOS – 5-YEAR SUMMARY

	2018	2017	2016	2015	2014
Net sales, SEK million	188	148	138	120	85
Gross margin, non-durable goods, %	77	78	80	78	77
Gross margin, %	72	76	74	71	76
EBITDA, %	16	15	12	16	13
Operating margin, %	7	5	2	6	9
Net margin, %	7	4	1	4	6
Total assets, MSEK	587	539	350	204	200
Equity/assets ratio, %	92	94	90	91	89
Earnings per share, SEK	0,48	0,25	0,07	0,24	0,25
Equity per share, SEK	20,47	19,26	13,40	8,59	8,29
Share price at closing day, SEK	132,00	94,00	88,00	58,50	34,30
Average number of employees	35	29	24	18	15

In order to succeed in keeping a high growth rate at the same time as having a high degree of innovation, the company has focused on strategically important issues such as product development in cooperation with world-leading researchers, universities and clinics, as well as building up market organization and sales capacity. At the same time, the company has freed resources by having non-strategic parts such as production and administration mainly outsourced to external parties.

In 2018, great progress was made in XVIVO Perfusion's most important product area - warm perfusion of lungs. Some of the most important advances were that more clinics adopted the XPS™ technology and that the collaboration with United Therapeutics (an innovative player in lung evaluation) was expanded. During the year, the organization within both clinic support and clinical trials has also been strengthened. These advances and investments enabled a sales increase of about 50 percent for warm perfusion products and that warm perfusion products for the first time ever achieved 50 percent of sales in the fourth quarter.

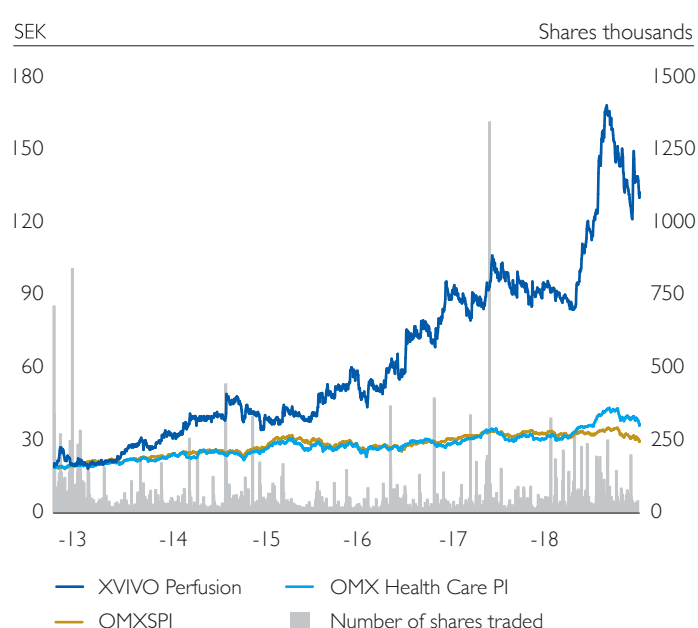
XVIVO Perfusion is the market leader in cold preservation of lungs and to strengthen and maintain that position in the long term, Perfadex® Plus was launched during the year, which is an improved 'ready to use' version of the company's largest product Perfadex®. The product has been approved for marketing and has been launched in Europe and the United States. Perfadex® Plus is a unique preparation that has been patent-pending and has been well received by the clinics as it simplifies its use and increases patient safety.

With this path, the company has also during 2018 managed to generate good gross margin and profit, while strong investments in R&D, regulatory competence and expansion of the customer support organization were made during the year.

### Research and development

XVIVO Perfusion conducts its own product development for the most part, while research is mainly conducted in collaboration with world-leading institutions and researchers in all large markets in the

### SHARE PRICE DEVELOPMENT SINCE LISTING



world. In addition to the study on STEEN Solution™ and XPS™ in the US, the company also conducts development with a number of other centers in the world.

Of the total operating expenses of SEK 123 million (106) for the year, research and development costs represented SEK 48 million (44) which corresponds to 39 (37) per cent. In addition, SEK 47 million (28) in research and development costs during the year has been capitalized as an intangible asset. SEK 19.0 million (11.9) is attributable to investments in the continued NOVEL study with the intention of obtaining a PMA approval for STEEN Solution™ and XPS™, SEK 26.9 million (14.7), is attributable to investments in the heart transplant project with the intention of reaching market approval in the US and Europe and SEK 1.3 million (1.6) is attributable to expenses for reaching regulatory approvals for the other product portfolio.

During the year, the company's PMA application for XPS™ with STEEN Solution™ was submitted to the FDA. This was an important milestone for XVIVO Perfusion, which worked intensively for seven years to reach this point. The application is evaluated by the FDA and the company continues to have a good dialogue with the FDA.

Within the company's important product area for future growth, heart transplantation, development work has been accelerated during the year with a larger organization. The important advances that can be mentioned are, among other things, that the new transportable heart preservation machine was preclinically tested with success and an application for clinical multi-center testing was submitted. In parallel, the company has intensified the production development of the new unique heart preservation solution.

In addition, analysis of the clinical study with PrimECC® has shown that the product is safe and has shown promising clinical results. The company has made the decision to set up production on the product and carry out a multicenter study.

The company also continues to support clinical phase research to extend the use of warm perfusion using STEEN Solution™ to the liver and to the administration of drugs to isolated organs. This is part of the long-term aim of becoming the global leader in the field of organ perfusion, initially in the thoracic region, but later in the field of liver and kidney transplants as well. In the longer term the aim is to treat isolated organs and tissues still in the body using tailored techniques to avoid problems of adverse effects in other parts of the body. One example of this is cancer treatment. The competence in these areas is also used to develop PrimECC®.

### **Significant risks and uncertainty factors**

There are a number of risk factors which impact XVIVO Perfusion AB's business and which may do so in the future.

The risks are presented in the following areas:

- Market risks
- Operational risks
- Legal and regulatory risks
- Financial risks

#### **Market risks**

Lung transplantations are an expensive but life-saving procedure for which there are no medical treatment alternatives. The cost of a transplantation is largely balanced by the decreased treatment

costs that are otherwise associated with the patient. Today there is a lack of organs, which is most often the main obstacle to performing more transplants. Other market risks are access to funding and medical resources at clinics in the world. In the assessment of XVIVO Perfusion, the business is not currently significantly impacted by changes in the world economy.

#### **Operational risks**

These primarily comprise risks that limit or prevent XVIVO Perfusion from developing, manufacturing and selling qualitative, effective and safe products. The risks have been identified and essentially reduced to manageable levels, amongst other things by the signing of agreements with suppliers, collaboration partners and customers. XVIVO Perfusion is a company of limited size and the organization is still in the process of being built up. XVIVO Perfusion's future development is partly dependent on key persons with specialist knowledge remaining in the organization.

#### **Legal and regulatory risks**

The market for XVIVO Perfusion is impacted by the appropriate legislation and other regulations. Changes in legislation or political decisions may impact XVIVO Perfusion's ability to run or develop the business. The clinical NOVEL study in the US continues with the aim of achieving PMA approval in the American market (the current approval is a so-called HDE, Humanitarian Device Exemption) for STEEN Solution™ and XPS™.

Due to the nature of the business there is a risk of claims for damages and liability. In order to protect the Group against the economic effects of any claims, XVIVO Perfusion is insured against general and business-related claims for damages.

#### **Financial risks**

XVIVO Perfusion has most of its sales in other currencies than SEK. The US dollar and the Euro are the most important currencies. Expenses are largely in SEK but a considerable portion is in USD. XVIVO Perfusion does not currently hedge its revenues in foreign currency, which means that there is a currency risk for the business (see note 27 for further information).

#### **Insurance**

XVIVO Perfusion regularly meets insurance brokers and advisors both locally and globally, which ensures that the business and the area of responsibility are correctly insured.

#### **Environment and responsibility**

XVIVO Perfusion's business does not entail any particular environmental risks and does not require any special environmentally related permits or decisions from authorities. XVIVO Perfusion assesses that the company runs its business in accordance with the applicable health and safety rules and offers its employees a safe and healthy environment. As lung transplantation is a life-saving treatment, the availability of products is governed by regulatory authorities. Wherever possible, the company tries to choose the form of transport that has the smallest environmental footprint. The company constantly works to reduce its environmental footprint. XVIVO Perfusion is a global company, where traveling cannot be entirely avoided but the number of trips can be limited by increasing the number of telephone and video meetings.

#### **Legal disputes**

The company was not involved in any legal disputes during 2018.

## 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.

## Guidelines for remuneration of senior management

The principles for remuneration and other terms and conditions of employment for the CEO and senior management were adopted by the Annual General Meeting on April 27, 2018 in accordance with the following:

Remuneration of the CEO and other senior management consists of a basic salary, variable remuneration and pension. The senior management group currently consists of five people. The composition and size of this group can change over time as a result of the development of the business.

The division between basic salary and variable remuneration shall be in proportion to the executive's responsibility and authority. Annual variable remuneration for the CEO is capped at six months' salary. For other senior management annual variable remuneration is capped at three months' salary. Annual variable remuneration for the CEO and other senior management is based on the outcome of various parameters compared with predetermined objectives. The parameters relate to the company's sales, results and individually set objectives. Levels of remuneration shall be in line with market rates. Notice of termination of employment for the CEO and for other senior management shall be no more than six months. If the company serves notice of termination of employment, severance pay of no more than 12 months' salary shall be paid to the CEO. Other senior management do not receive any severance pay upon termination of their employment.

Each year the Board shall evaluate whether some form of share-related incentive program is to be proposed to the Annual General Meeting.

The company currently has two warrant programs outstanding. For participants in countries where allocation of warrants is not appropriate, the Board has decided, instead of issuing warrants, to introduce an alternative cash-based incentive program. Such an alternative cash-based program is designed, as far as is practically possible, so that it corresponds to the conditions of the warrant programs.

Members of the Board elected at a general meeting of shareholders shall in special cases be able to receive a fee for services in their respective areas of competence which are not a part of their work on the Board. A fee in line with market rates shall be paid for these services and this fee shall be approved by the Board.

The Board of Directors will propose to the 2018 Annual General Meeting that the principles for remuneration shall remain unchanged up until the 2020 Annual General Meeting. The Board shall be entitled to depart from these guidelines if in an individual case there is reason to do so.

## Parent Company

The business focuses on sales outside the Americas, global research and development and global marketing. Expenses attributable to the Board and to the company's shares being listed on Nasdaq Stockholm are also borne by the Parent Company. During the year SEK 49 million (32) was capitalized, of which SEK 48 million (29) was capitalized in intangible assets and SEK 2 million (3) was capitalized in tangible assets.

## Proposal of profit appropriation

The following non-restricted equity are at the disposal of the Annual General Meeting:

Share premium reserve	472 345 968 SEK
Retained earnings	-45 939 478 SEK
Net income for the year	7 797 711 SEK
	<hr/>
	434 204 201 SEK

The Board of Directors propose that the non-restricted equity is allocated as follows:

To be carried forward	434 204 201 SEK
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The financial reports were approved for issuance by the Board of the Parent Company on April 2, 2019.

Regarding the company's results and financial position, please refer to the following income statements and balance sheets, together with the accompanying notes to the financial statements.

# CORPORATE GOVERNANCE REPORT

"Good corporate governance means ensuring that companies are run sustainably, responsibly and as efficiently as possible on behalf of their shareholders. The confidence of legislators and the public that companies act responsibly is crucial if companies are to have the freedom to realise their strategies to create value. The confidence of existing and potential shareholders that such is the case is crucial to their interest in investing in companies, thus securing corporate Sweden's freedom to develop and its supply of competence and venture capital." (Extract from the Swedish Corporate Governance Code)

XVIVO Perfusion AB (publ) is a Swedish public limited company listed on Nasdaq Stockholm's main market since November 28, 2016. The corporate governance policies applied by XVIVO are based on Swedish legislation, primarily the Swedish Companies Act and the Swedish Annual Accounts Act, and NASDAQ Stockholm AB's regulations. The company has applied the Swedish Corporate Governance Code ("the Code") as from the day the company's shares were listed on Nasdaq Stockholm's main market. XVIVO Perfusion has deviated from the Code only regarding the design of alternative cash-based incentive programs for participants in countries where allocation of warrants is not appropriate. The time period of the two alternative cash-based incentive programs, which as far as is practically possible have been designed so that they correspond to the terms and conditions of the two warrant programs outstanding, is less than the three years stipulated in the Code. The two warrant programs outstanding are further described in the 2018 Annual Report in Note 23. Further information on corporate governance in XVIVO Perfusion is to be found at [www.xvivoperfusion.com](http://www.xvivoperfusion.com).

## Shareholder structure

According to Euroclear's official shareholder register, XVIVO Perfusion had 5 137 shareholders at December 31, 2018. XVIVO Perfusion AB's (publ) ten largest shareholders at December 31, 2018 are presented below:

Shareholder	Number of shares	Shares and votes, %
Bure AB Equity	4 291 483	16,3
Swedbank Robur	1 630 000	6,2
Eccenovo AB	1 500 000	5,7
Fjärde AP fonden	1 250 000	4,7
Norron Fonder	1 249 590	4,7
Oppenheimer	1 000 000	3,8
Thomas Olausson	900 000	3,4
Handelsbanken Liv	557 367	2,1
Försäkringsaktiebolaget, Avanza Pension	478 386	1,8
Tredje AP fonden	461 236	1,7
Other shareholders	13 318 062	49,6
Total	26 402 496	100,0

Source: Euroclear Sweden's shareholder register at December 31, 2018.

## Shares

At December 31, 2018 the share capital of XVIVO Perfusion AB (publ) was SEK 674 815 allocated among 26 190 496 shares. The shares are traded on Nasdaq Stockholm's main market. All shares carry the same number of votes and entitle shareholders to equal shares in XVIVO Perfusion's assets and earnings.

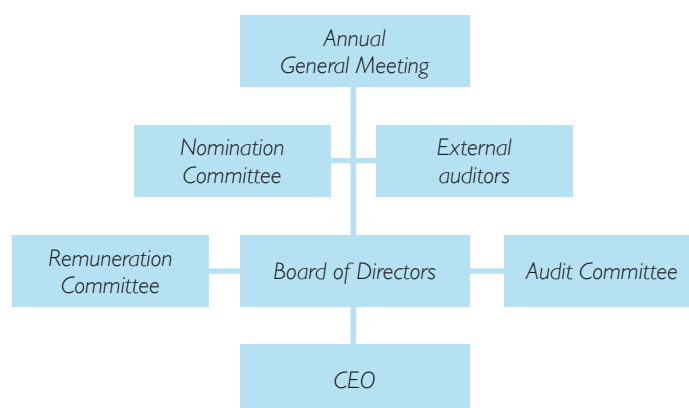
In June, 2018, 212 000 warrants of series 2016/2018 were used for subscription for as many shares and the company received SEK 19 126 640 in the share issue. The share capital increased with SEK 5 418 and the excess part, SEK 19 121 222, was recognized as share premium.

At the XVIVO Perfusion Annual General Meeting on April 27, 2018, it was resolved that for the period until the next Annual General Meeting on one or more occasions, the Board of Directors are authorized to issue a maximum of 2,619,000 shares. The equivalent of just under 10 % of the total number of shares and votes in the company.

A resolution was adopted at XVIVO Perfusion's Annual General Meeting held on April 27, 2018 to issue no more than 315 000 warrants entitling warrant holders to subscribe for new shares. The warrants will be offered to employees in the two Swedish group companies. If the warrants are fully utilized, the share capital will increase by SEK 8 190, corresponding to dilution of approximately 1 percent of the total number of shares and votes in the company.

## Corporate governance

The figure below illustrates XVIVO Perfusion's corporate governance model and who appoints the central bodies.



## Annual General Meeting

XVIVO Perfusion's highest decision-making body is the general meeting of shareholders. The Annual General Meeting shall be held within six months of the end of the financial year. A notice convening the AGM is issued no earlier than six and no later than four weeks prior to the meeting. All shareholders entered in the shareholders' register and who have notified their intent to attend in time are entitled to participate and vote at the meeting. Shareholders who are unable to attend may be represented by a proxy.

## Annual General Meeting 2018

The most recent Annual General Meeting was held on April 27, 2018 in Gothenburg. The Annual General Meeting resolved to re-elect Gösta Johannesson, Folke Nilsson, Erik von Schenk and Camilla Öberg as Board members. Yvonne Mårtensson and Alans Raffensperger were elected as new Board members. Gösta Johannesson was elected as Chairman of the Board. A resolution was passed to adopt Board fees of a total of SEK 1 035 000, of which SEK 205 000 SEK to the Chairman, SEK 130 000 SEK to each of the other Board members and SEK 40,000 to the Chairman of the Audit Committee, SEK 40,000 SEK to the Chairman of the

Remuneration Committee and SEK 25,000 to each of the other members of these committees.

The proposal not to pay any dividend for the financial year 2017 was approved.

The Board was authorized, for the period up until the next Annual General Meeting, to decide on one or more occasions to make a new issue of a maximum of 2 619 000 shares, corresponding to slightly less than 10% of the total number of shares and votes in the company.

The proposed policies for remuneration and other terms of employment for the executive management were adopted. The proposed issue of 315 000 warrants entitling warrant holders to subscribe for new shares was approved.

### **Annual General meeting 2019**

The Annual General Meeting will be held on April 25, 2019 at 3:00 p.m. at World Trade Center (on the floor below XVIVO Perfusion's premises) in Gothenburg at Möllans gata 10. Shareholders wishing to attend the Annual General Meeting must be registered in the register of shareholders kept by Euroclear Sweden AB on April 17, 2019.

Furthermore, XVIVO Perfusion requests shareholders to notify the company that they will attend no later than April 23, 2019. Notification shall be sent to Kristoffer Nordström, either in writing to the address XVIVO Perfusion AB (publ), Box 53015, 400 14 Göteborg, by telephone on +46 (0)31 788 21 64, by fax on +46 (0)31 788 21 69 or by email to [kristoffer.nordstrom@xvivoperfusion.com](mailto:kristoffer.nordstrom@xvivoperfusion.com). Shareholders shall state their name, personal or corporate identity number, address, telephone number and the number of shares held. For shareholders who are represented by another party, a proxy shall be sent together with the notification. Any party representing a legal entity must produce a copy of the certificate of incorporation or equivalent authorization documents showing the authorized signatory for the company.

In order to be entitled to attend the AGM, shareholders whose shares are registered through a bank, a private securities broker or some other nominee must temporarily re-register their shares in their own name. In order for such re-registration to be entered in the register of shareholders on April 17, 2019, shareholders should well in advance before this date instruct their nominees to effect such re-registration.

Shareholders who wish to have an issue addressed by the general meeting must make a written request to this effect to the Board. Any such request to address an issue must be sent to XVIVO Perfusion AB (publ), Att: Styrelsens ordförande, Box 53015, 400 14 Göteborg, and must be received by the Board no later than seven weeks prior to the general meeting, or in any case in time for the issue, if required, to be included in the notice convening the general meeting.

Taking into account the composition of the company's shareholders, it has not been considered warranted or justified given the company's financial position to offer simultaneous interpretation to another language and translation of all or parts of the material for the meeting, including the minutes.

## **The Board**

### **General**

The Board is responsible for the company's administration of its affairs and organization. At the Annual General Meeting held in April 2018, six Board members were elected with competence in both medical devices and biotechnology as well as within the areas of finance and strategy. The company's CFO Christoffer Rosenblad served as the Board's secretary. In 2018, the Board held 13 meetings (15), and minutes were kept at all meetings.

Board members' attendance at each meeting is presented in the following table:

Name	Dependent*	Attendance Board meetings	Attendance Remuneration Committee	Attendance Audit Committee
Gösta Johannesson	Yes	13/13	3/3	2/2
Erik von Schenck		11/13	4/4	
Folke Nilsson		13/13		4/4
Camilla Öberg		13/13		4/4
Yvonne Mårtensson		10/10	3/3	
Alan Raffensperger		9/10		2/2
Fredrik Mattsson	Yes	3/3	1/1	
Semmy Rulf		3/3	1/1	

\* Dependent in relation to the company's major shareholders

The CEO and CFO have presented issues at the Board meetings. Remuneration and other benefits paid to the Board of XVIVO Perfusion are detailed in Note 6 of the 2018 Annual Report.

### **The Board's work**

Each year, the Board is to convene for a minimum of seven scheduled meetings, equally distributed over the year, and one statutory Board meeting. The meetings are normally held in the form of physical meetings at XVIVO Perfusion's headquarters in Gothenburg. If it is preferable for practical reasons, the meetings are held by telephone or in special cases per capsulam.

The Chairman leads and organizes the Board's work. A proposed agenda and decision data regarding the items to be addressed at the meeting are sent ahead of each meeting. The proposed agenda is drawn up by the CEO in consultation with the Chairman. Items presented to the Board are for information purposes, discussion or decision. Decisions are only taken following discussion and after all members present have been given the opportunity to be heard. The Board's extensive experience in various areas generates constructive and open discussion. During the year, no Board member registered dissent with regard to any Board decision. Any open issues are followed up on an ongoing basis.

One of the meetings held during the year focused on strategic questions. In addition, parts of the Board have met on several occasions to discuss questions they have been tasked with investigating further. The Board's formal work plan was adopted at the statutory Board meeting on April 27, 2018. The Board's formal work plan is reviewed at least once a year. The plan regulates areas such as the allocation of responsibilities, the number of scheduled meetings, the form of notifications, decision data and minutes, conflicts of interest, mandatory items to be submitted by the CEO to the Board and authorized signatories. The Board addresses ongoing items such as business conditions, interim reports, budgets, strategies and external information.

In addition to the Board material, the CEO distributes monthly reports containing a financial report and a description of current

events in operations and in the market. The aim is to keep the Board informed about the development of the company's operations to enable the Board to take well-founded decisions. Once each year, the Board holds a meeting that evaluates the work of the CEO, which the executive management does not attend. The Board ensures the quality of the financial reporting through its own work and through contact with the auditor. The company's auditor participated at the meeting addressing the annual accounts, where the audit results were reported.

The Board evaluates its work annually through a self-evaluation procedure where each Board member assesses just over fifty statements about the Board's role and function, the Board meetings, Board material, Board members, the Chairman of the Board and the CEO. The answers are compiled by the Chairman of the Board and are presented to the Board and Nomination Committee. The answers form the basis of constant development of the work of the Board.

### **Members of the Board**

XVIVO Perfusion's Board comprises six members, including the Chairman. For details about the Board members and their shareholdings, please refer to the 2018 Annual Report, page 56, and the company's website ([www.xvivoperfusion.com](http://www.xvivoperfusion.com)).

### **Remuneration Committee**

At the statutory Board meeting held on April 27, 2018 XVIVO Perfusion's Board appointed a Remuneration Committee, which prepares proposals concerning questions of remuneration. The Remuneration Committee's areas of responsibility are defined in the Board's formal work plan and in the Remuneration Committee's instruction. The Group's guidelines for remuneration of executive management are included in the Management Report on page 30 of the 2018 Annual Report and on the company's website ([www.xvivoperfusion.com](http://www.xvivoperfusion.com)). The Remuneration Committee consists of three Board members: Gösta Johannesson (Chairman of the Remuneration Committee), Yvonne Mårtensson and Erik von Schenk.

### **Audit Committee**

At the statutory Board meeting held on April 26, 2017 XVIVO Perfusion's Board appointed an Audit Committee. The tasks of the Audit Committee are described in an instruction for the Audit Committee. The purpose of the work of the Audit Committee is to assist XVIVO Perfusion's Board in questions regarding financial reporting, auditing and risk management. The Audit Committee is a preparatory body and the Board has overriding responsibility for questions related to auditing. The members of the Audit Committee shall consist of at least three Board members, and these will be appointed by the Board at the statutory Board meeting or whenever otherwise necessary. The members of the Audit Committee may not be company employees. At least one member shall be independent in relation to the company's major shareholders and should have accounting or auditing competence. The Audit Committee consists of three Board members: Camilla Öberg (Chairman of the Audit Committee), Alan Raffensperger and Folke Nilsson.

The Audit Committee shall in particular monitor (i) the audit of the Annual Report and the consolidated financial statements, (ii) transactions with related parties, important accounting principles and important correspondence between the company's auditors and management, (iii) the effectiveness of the company's internal controls regarding financial reporting, (iv) the company's routines concerning comments on the company's accounts, internal control and auditing,

(v) the scope, focus and quality of auditing work, including follow-up of the audit performed, (vi) budgeted and actual auditing expenses, (vii) the auditors' recommendations, conclusions, observations and proposals after an audit has been performed, (viii) the auditor's impartiality and independence and in this connection pay particular attention to whether the auditor provides the company with other services than auditing work and (ix) assist in the drawing up of proposals for adoption by the Annual General Meeting regarding election of an auditor.

### **Management team**

For information on members of the Management team and their shareholdings, please refer to page 57 of the 2018 Annual Report and the company's website ([www.xvivoperfusion.com](http://www.xvivoperfusion.com)). XVIVO Perfusion's Management team consist of six members, CEO included. The Management team holds competence and experience from research and development, quality assurance, regulatory affairs, marketing, production and distribution of medical equipment and finance.

The Management team meets once a week. Since there is a member represented on each site in Gothenburg, Lund and Denver, US, video conferences are frequently used. Three times a year the team meets physically for meetings with a more strategic focus. The instruction for the Board of Directors and the CEO was determined on the statutory board meeting on April, 27, 2018, and regulates the segregation of duties between the Board of Directors, the Chairman of the Board and the CEO. The operative management is based on the decision-making that has been determined by the Board.

### **Election of auditor**

The 2017 Annual General Meeting appointed KPMG AB as the company's audit firm, with authorized public accountant Jan Malm as the auditor in charge, for the period up until the end of the 2020 Annual General Meeting. Jan Malm has reported his observations from the audit to the Board. The annual report, accounts and the administration of the Board and the CEO were examined within the scope of the above work.

### **Nomination Committee**

The Nomination Committee for the 2019 Annual General Meeting has been appointed in accordance with the principles adopted at the 2018 Annual General Meeting. These stipulate that the Chairman of the Board – no later than the end of the third quarter of 2018 – shall contact the three largest shareholders of XVIVO Perfusion AB (publ) on the basis of known shareholdings at the end of August 2018 and ask them to appoint one member each to be included in the Nomination Committee. If any of the three shareholders waives their right to appoint a member of the Nomination Committee, or if a member resigns from the Nomination Committee without being replaced by a new member appointed by the same shareholder, the next shareholder in terms of size shall be afforded the opportunity of appointing a member of the Nomination Committee. Unless otherwise agreed by the members of the committee, the Chairman of the Nomination Committee shall be the committee member appointed by the largest shareholder. The mandate period shall run until a new Nomination Committee has taken over.

If during the mandate period of the Nomination Committee one or more shareholders who have appointed Nomination Committee members are no longer one of the three largest shareholders, committee members appointed by these shareholders shall step down and the shareholder or shareholders who have become one of the three largest shareholders shall be entitled to appoint their

committee members. Except in special circumstances, there shall be no changes in the composition of the Nomination Committee if only marginal changes in the number of votes have occurred or if the change occurs later than three months before the Annual General Meeting.

The composition of the Nomination Committee was published on the website at least six months before the Annual General Meeting.

The work of the Nomination Committee includes making proposals before the Annual General Meeting regarding (i) election of a Chairman for the meeting, (ii) a resolution regarding the number of Board members, (iii) election of and a resolution regarding fees for the Chairman of the Board and the Board members, (iv) election of and a resolution regarding the fees for the auditor, and (v) a resolution regarding a new Nomination Committee procedure, if the Nomination Committee deems this appropriate.

### **The Board's description of the key elements in the company's system for internal control, follow-up and risk management.**

The Board is responsible for internal control pursuant to the Swedish Companies Act. This report is limited to a description of how the internal control regarding financial reporting is organized. It pertains to the 2018 financial year.

The objective of internal financial control regarding financial reporting at XVIVO Perfusion is to create an efficient decision process in which requirements, targets and frameworks are clearly defined. Ultimately, the controls aim to protect the company's assets and, thereby, the shareholders' investments.

#### **Control environment**

The control environment forms the basis for the internal control. XVIVO Perfusion's control environment includes healthy values, integrity, competence, leadership philosophy, organizational structure, responsibility and authorities. XVIVO Perfusion's internal work procedures, instructions, policies, guidelines and manuals provide guidance to employees. At XVIVO Perfusion, a clear allocation of roles and responsibilities for efficient management of operational risks is ensured through measures including the Board's formal work plan and the instruction for the CEO. The CEO reports regularly to the Board. The CEO is responsible, in terms of the operating activities, for the system of internal controls required to construct a control environment for significant risks. XVIVO Perfusion also has guidelines and policies for financial governance and follow-up as well as for communication issues etc. The Group's four companies essentially have the same structure, financial system and accounting plan. XVIVO Perfusion continually reviews this system.

#### **Risk assessment and control activities**

XVIVO Perfusion works with risk analysis on an ongoing basis to identify potential sources of error in the financial reporting. Traceability in the financial statements is ensured by good documentation. A system has been developed which follows up various activities in detail and compares them with the budget. The follow-up ensures communication with the different parts of the company, so that the Finance Department is also well acquainted with future activities and any deviations from the budget. The work on securing the processes where it has been identified that the risk of material error in the financial reporting may be assumed to be relatively higher than in other processes is continuously ongoing.

Normal control activities comprise monthly reconciliation of accounts and supplementary checks. The aim of all control activities is to prevent, detect and correct any errors or deviations in the financial reporting. The company intends to continue developing and following up selected control activities during the coming financial year. The company has a system for scanning invoices from suppliers which includes automatic approval control, and this raises the level of security in the internal control.

#### **Follow-up**

The Board continuously evaluates the information submitted by the executive management, which comprises both financial information and material issues pertaining to the internal control. The Board continuously follows up the effectiveness of the internal control, which, in addition to ongoing updates for deviations, is carried out, inter alia, by ensuring that measures are implemented in respect of the proposed actions that may have arisen after external audits.

#### **Information och communication**

Proper disclosures and clear lines of communication, both internal and external, mean that all parts of operations exchange and report relevant, significant operational data in an efficient manner. To achieve this, XVIVO Perfusion has issued a communication policy regarding information management in the financial process, as well as policies and guidelines for other types of information. The executive management has communicated these to employees and employees are acquainted with the communication policy. Guidelines have been set out for how communication with external parties should take place, who is authorized to provide certain types of information and when a log book should be kept. The ultimate aim of the aforementioned policies is to ensure compliance with disclosure requirements pertaining to legislation and listing agreements, and that investors receive the correct information in time.

#### **Internal auditing**

XVIVO Perfusion has so far not had reason to set up a special internal audit function in the financial area. This is because the company is relatively small in size and the constantly ongoing work on internal control has led to awareness of internal control in the Group being perceived as high and to a number of control activities being in place. The issue of a special internal audit function will be reviewed as the company grows.

# CONSOLIDATED STATEMENT OF NET INCOME

JANUARY 1 – DECEMBER 31

SEK thousands	Note	2018	2017
Net sales	2	187 868	148 342
Cost of goods sold		-51 915	-34 946
<b>Gross income</b>	3	<b>135 953</b>	<b>113 396</b>
Selling expenses		-47 948	-43 702
Administrative expenses		-22 519	-20 045
Research and development costs		-47 931	-39 469
Other operating revenues	4	1 281	970
Other operating expenses	5	-4 836	-4 044
<b>Operating income</b>	6, 7, 8, 9, 11	<b>14 000</b>	<b>7 106</b>
Financial income		4 252	1 489
Financial expenses		-754	-1 143
<b>Net financial income</b>	10, 11	<b>3 498</b>	<b>346</b>
<b>Income before taxes</b>		<b>17 498</b>	<b>7 452</b>
Tax on income for the year	13	-4 813	-1 192
<b>Net income for the year</b>		<b>12 685</b>	<b>6 260</b>
<b>Net income for the year attributable to:</b>			
Parent Company shareholders		12 685	6 260
Earnings per share before dilution, SEK		0,48	0,25
Earnings per share after dilution, SEK*		0,48	0,24
Average number of outstanding shares before dilution		26 302 385	25 440 188
Average number of outstanding shares after dilution*		26 302 385	25 693 549
Number of shares at closing day before dilution		26 402 496	26 190 496
Number of shares at closing day after dilution*		26 402 496	26 402 496

\* After dilution. See Note 23 for information on warrants program.

# CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME

JANUARY 1 – DECEMBER 31

SEK thousands	Note	2018	2017
<b>Net income for the year</b>		<b>12 685</b>	<b>6 260</b>
<b>Other comprehensive income</b>			
<i>Items that have been or may be reclassified to the income statement</i>			
Exchange-rate differences		4 875	-5 187
Tax attributable to items that have been or may be transferred to the income statement	13	-473	464
<b>Total other comprehensive income for the year, net after tax</b>	22	<b>4 402</b>	<b>-4 723</b>
<b>Total comprehensive income for the year</b>		<b>17 087</b>	<b>1 537</b>
<b>Total comprehensive income for the year attributable to:</b>			
Parent Company shareholders		17 087	1 537

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK thousands	Note	2018-12-31	2017-12-31
<b>ASSETS</b>	26, 27		
<b>Non-current assets</b>			
INTANGIBLE ASSETS	14		
Capitalized development expenditure		210 460	173 430
Patents, licenses and trademarks		3 624	3 472
Goodwill		65 614	65 273
	15		
PROPERTY, PLANT AND EQUIPMENT			
Machinery, equipment, fixtures and fittings		15 615	16 277
FINANCIAL ASSETS			
Deferred tax asset	13	13 548	15 395
Other financial assets		71	71
<b>Total non-current assets</b>		<b>308 932</b>	<b>273 918</b>
<b>Current assets</b>			
INVENTORIES	17	36 387	30 703
CURRENT RECEIVABLES			
Accounts receivable - trade	19	43 716	24 997
Tax assets		-	3 341
Other receivables		3 209	2 434
Prepaid expenses and accrued income	20	7 304	7 825
CASH AND CASH EQUIVALENTS	21	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>TSEK</b>	Note	2018-12-31	2017-12-31
<b>SHAREHOLDERS' EQUITY</b>	22, 23		
<b>Shareholders' equity attributable to Parent Company shareholders</b>			
Share capital		675	670
Other capital contributed		486 860	467 661
Reserves		13 021	8 618
Retained earnings incl. net income for the year		39 921	27 383
<b>TOTAL SHAREHOLDERS' EQUITY</b>		<b>540 477</b>	<b>504 332</b>
<b>LIABILITIES</b>			
Other provisions		1 329	1 351
Deferred tax liability	13	2 233	1 961
<b>Total long-term liabilities</b>		<b>3 562</b>	<b>3 312</b>
Accounts payable		16 333	11 121
Current tax liability		944	45
Other liabilities		1 100	1 043
Accrued expenses and deferred income	25	24 196	18 687
<b>Total current liabilities</b>	26, 27, 28	<b>42 573</b>	<b>30 896</b>
<b>TOTAL LIABILITIES</b>		<b>46 135</b>	<b>34 208</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>		<b>586 612</b>	<b>538 540</b>

# CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK thousands	Attributable to Parent Company shareholders				Non-controlling interests	Total shareholders' equity
	Share capital	Other capital contributed	Reserves	Retained earnings incl. net income for the year		
<b>Opening shareholders' equity at January 1, 2017</b>	<b>604</b>	<b>280 890</b>	<b>13 341</b>	<b>21 641</b>	<b>-</b>	<b>316 476</b>
COMPREHENSIVE INCOME FOR THE YEAR						
Net income for the year	-	-	-	6 260	-	6 260
Other comprehensive income for the year	-	-	-4 723	-	-	-4 723
Total comprehensive income for the year	-	-	-4 723	6 260	-	1 537
TRANSACTIONS WITH GROUP'S SHAREHOLDERS						
<i>Contributions from and value transfers to shareholders</i>						
New share issue minus transaction expenses, net after tax*	66	186 424	-	-	-	186 490
Premium paid upon issue of warrants	-	347	-	-	-	347
Total contributions from and value transfers to shareholders	66	186 771	-	-	-	186 837
<i>Changes in participating interests in subsidiaries</i>						
Acquisition from non-controlling interests**	-	-	-	-518	-	-518
Total transactions with Group's shareholders	66	186 771	-	-518	-	186 319
<b>Closing shareholders' equity at December 31, 2017</b>	<b>670</b>	<b>467 661</b>	<b>8 618</b>	<b>27 383</b>	<b>-</b>	<b>504 332</b>
<b>Opening shareholders' equity at January 1, 2018</b>	<b>670</b>	<b>467 661</b>	<b>8 618</b>	<b>27 383</b>	<b>-</b>	<b>504 332</b>
Adjustment for retroactive change***	-	-	-	-146	-	-146
<b>Adjusted shareholders' equity at January 1, 2018</b>	<b>670</b>	<b>467 661</b>	<b>8 618</b>	<b>27 237</b>	<b>-</b>	<b>504 186</b>
COMPREHENSIVE INCOME FOR THE YEAR						
Net income for the year	-	-	-	12 684	-	12 684
Other comprehensive income for the year	-	-	4 403	-	-	4 403
Total comprehensive income for the year	-	-	4 403	12 684	-	17 087
TRANSACTIONS WITH GROUP'S SHAREHOLDERS						
<i>Contributions from and value transfers to shareholders</i>						
New share issue minus transaction expenses, net after tax**	5	19 017	-	-	-	19 022
Premium paid upon issue of warrants	-	182	-	-	-	182
Total contributions from and value transfers to shareholders	5	19 199	-	-	-	19 204
<b>Closing shareholders' equity at December 31, 2018</b>	<b>675</b>	<b>486 860</b>	<b>13 021</b>	<b>39 921</b>	<b>-</b>	<b>540 477</b>

\* Transaction costs in connection with new share issue amount to SEK 104 thousand (9 294).

\*\* Acquisition of the last warrants outstanding in Vivoline Medical AB.

\*\*\* Adjustment of the opening balance relates to effects from the implementation of IFRS 15.

# CONSOLIDATED CASH FLOW STATEMENT

JANUARY 1 – DECEMBER 31

SEK thousands

	Note	2018	2017
<b>Operating activities</b>	30		
Income after financial items		17 497	7 452
Adjustment for non-cash items		16 072	13 183
Taxes paid		628	-2 657
		<b>34 197</b>	<b>17 978</b>
Increase (-)/Decrease (+) in inventories		-2 976	822
Increase (-)/Decrease (+) in operating receivables		-17 380	-1 013
Increase (-)/Decrease (-) in operating liabilities		9 786	4 403
<b>Cash flow from operating activities</b>		<b>23 627</b>	<b>22 190</b>
<b>Investing activities</b>			
Acquisition of intangible fixed assets		-48 044	-29 310
Acquisition of property, plant and equipment		-6 662	-5 624
Divestment of property, plant and equipment		1 508	-
Acquisition of subsidiaries, net impact on liquidity		-	-518
Acquisition of other financial assets		-	-71
<b>Cash flow from investing activities</b>		<b>-53 198</b>	<b>-35 523</b>
<b>Financing activities</b>			
Warrants program		182	347
New share issue		19 022	184 451
<b>Cash flow from financing activities</b>		<b>19 204</b>	<b>184 798</b>
<b>Cash flow for the year</b>		<b>-10 367</b>	<b>171 466</b>
Cash and cash equivalents at beginning of year		195 322	24 871
Exchange-rate difference in cash and cash equivalents		2 109	-1 015
<b>Cash and cash equivalents at end of year</b>	21	<b>187 064</b>	<b>195 322</b>

# INCOME STATEMENT FOR THE PARENT COMPANY

JANUARY 1 – DECEMBER 31

SEK thousands

	Note	2018	2017
Net sales	2	152 332	123 345
Cost of goods sold		-39 735	-28 462
<b>Gross income</b>	3	<b>112 597</b>	<b>94 883</b>
Selling expenses		-27 940	-27 175
Administrative expenses		-12 578	-9 736
Research and development costs		-46 074	-38 955
Other operating revenues	4	1 443	1 000
Other operating expenses	5	-4086	-4 899
<b>Operating income</b>	6,7,8,9,11	<b>23 362</b>	<b>15 118</b>
<b>PROFIT/LOSS FROM FINANCIAL ITEMS</b>			
Interest income and similar items		7 524	4 270
Interest expenses and similar items		-1 064	-5 160
<b>Income after financial items</b>	10,11	<b>29 822</b>	<b>14 228</b>
Appropriations	12	-19 537	-3 900
Tax on income for the year	13	-2 487	-2 486
<b>Net income for the year</b>		<b>7 798</b>	<b>7 842</b>

The parent company has no items to report as other comprehensive income, therefore a statement of comprehensive income is not presented.

# BALANCE SHEET FOR THE PARENT COMPANY

SEK thousands	Note	2018-12-31	2017-12-31
<b>ASSETS</b>	26, 27		
<b>Non-current assets</b>			
INTANGIBLE ASSETS	14		
Capitalized development expenditure		146 427	109 397
Patents, licenses and trademarks		2 726	2 300
PROPERTY, PLANT AND EQUIPMENT	15		
Machinery, equipment, fixtures and fittings		7 367	10 713
FINANCIAL ASSETS			
Participating interests in Group companies	16	161 174	161 174
Receivables from Group companies	18	37 575	40 707
Deferred tax liability	13	1 402	1 522
Other financial assets		71	71
<b>Total non-current assets</b>		<b>356 742</b>	<b>325 884</b>
<b>Current assets</b>			
INVENTORIES	17	13 695	7 304
CURRENT RECEIVABLES			
Accounts receivable - trade	19	17 587	12 105
Receivables to Group companies		1 532	145
Current tax assets		-	1 511
Other receivables		3 375	2 711
Prepaid expenses and accrued income	20	5 194	6 950
CASH AND BANK BALANCES	21	178 248	173 421
<b>Total current assets</b>		<b>219 631</b>	<b>204 147</b>
<b>TOTAL ASSETS</b>		<b>576 373</b>	<b>530 031</b>
SEK thousands	Note	2018-12-31	2017-12-31
<b>SHAREHOLDERS' EQUITY</b>	22, 23		
RESTRICTED EQUITY			
Share capital		675	670
Statutory reserve		20	20
Reserve for development costs		84 348	37 450
NON-RESTRICTED EQUITY	29		
Share premium reserve		472 346	453 146
Retained earnings		-45 939	-6 883
Net income for the year		7 798	7 842
<b>TOTAL SHAREHOLDERS' EQUITY</b>		<b>519 247</b>	<b>492 245</b>
<b>Untaxed reserves</b>	24	<b>10 150</b>	<b>8 913</b>
<b>PROVISIONS</b>			
Other provisions		1 329	1 351
<b>Total provisions</b>		<b>1 329</b>	<b>1 351</b>
<b>CURRENT LIABILITIES</b>	21		
Accounts payable		10 212	6 963
Liabilities to Group companies	18	21 720	9 365
Other liabilities		350	-
Accrued expenses and deferred income		271	252
Total current liabilities	25	13 094	10 942
<b>TOTAL LIABILITIES</b>	26, 27, 28,	<b>45 647</b>	<b>27 522</b>
<b>TOTAL SHAREHOLDER'S EQUITY AND LIABILITIES</b>		<b>57 126</b>	<b>28 873</b>
<b>SHAREHOLDERS' EQUITY</b>		<b>576 373</b>	<b>530 031</b>

# CHANGES IN SHAREHOLDERS' EQUITY FOR THE PARENT COMPANY

SEK thousands	Restricted shareholders' equity			Non-restricted shareholders' equity			Total share- holders' equity
	Share capital	Statutory reserve	Reserve for development costs	Share premium reserve	Retained earnings	Net income for the year	
Opening shareholders' equity at Jan 1, 2017	604	20	9 306	266 297	23 053	-1 792	<b>297 488</b>
Net income for the year	-	-	-	-	-	7 842	7 842
Other comprehensive income for the year	-	-	-	-	-	-	-
Total comprehensive income for the year	-	-	-	-	-	7 842	7 842
Proposed appropriation of profits	-	-	-	-	-1 792	1 792	-
New share issue minus transaction expenses, net after tax**	66	-	-	186 424	-	-	186 490
Premium paid upon issue of warrants	-	-	-	425	-	-	425
Allocation to reserve for development expenditure	-	-	28 144	-	-28 144	-	-
Closing shareholders' equity at December 31, 2017	670	20	37 450	453 146	-6 883	7 842	<b>492 245</b>
Net income for the year	-	-	-	-	-	7 798	7 798
Other comprehensive income for the year	-	-	-	-	-	-	-
Total comprehensive income for the year	-	-	-	-	-	7 798	7 798
Proposed appropriation of profits	-	-	-	-	7 842	-7 842	-
New share issue minus transaction expenses, net after tax**	5	-	-	19 017	-	-	19 022
Premium paid upon issue of warrants	-	-	-	182	-	-	182
Allocation to reserve for development expenditure	-	-	46 898	-	-46 898	-	-
Closing shareholders' equity at December 31, 2018	675	20	84 348	472 345	-45 939	7 798	<b>519 247</b>

\* Transaction costs in connection with new share issue amount to SEK 104 thousand (9 294).

# CASH FLOW STATEMENT FOR THE PARENT COMPANY

JANUARY 1 – DECEMBER 31

SEK thousands

	Note	2018	2017
<b>Operating activities</b>	30		
Income after financial items		29 822	14 228
Adjustment for non-cash items		13 821	13 563
Taxes paid		-504	66
		<b>43 139</b>	<b>27 857</b>
Increase (-)/Decrease (+) in inventories		-7 056	6 217
Increase (-)/Decrease (+) in operating receivables		-5 783	-3 928
Increase (-)/Decrease (-) in operating liabilities		-1 329	4 044
<b>Cash flow from operating activities</b>		<b>28 971</b>	<b>29 962</b>
<b>Investing activities</b>			
Investments in intangible fixed assets		-48 043	-29 069
Acquisition of property, plant and equipment		-709	-2 272
Acquisition of subsidiaries		589	-
Change in loan to Group company		-	-566
Acquisition of other financial assets		3 933	-22 848
Cash flow from investing activities		-	-71
<b>Kassaflöde från investeringsverksamheten</b>		<b>-44 230</b>	<b>-54 826</b>
<b>Financing activities</b>			
Warrants program		182	425
New share issue, net after transaction expenses		19 023	184 026
<b>Cash flow from financing activities</b>		<b>19 205</b>	<b>184 451</b>
<b>Cash flow for the year</b>		<b>3 946</b>	<b>159 587</b>
Cash and cash equivalents at beginning of year		173 421	13 730
Exchange-rate difference in cash and cash equivalents		881	104
<b>Cash and cash equivalents at end of year</b>	21	<b>178 248</b>	<b>173 421</b>

# SUPPLEMENTARY DISCLOSURES AND NOTES TO THE FINANCIAL REPORTS

Notes to the financial statements for the full year 2017 for the XVIVO Perfusion Group and its Parent Company, XVIVO Perfusion AB (publ), corporate identity number 556561-0424, with its registered office in Gothenburg, Sweden, visiting address Mössans gata 10, postal address Box 53015, SE-400 14 Göteborg. The Parent Company is listed on the Mid Cap list of NASDAQ Stockholm.

## NOTE 1. ACCOUNTING POLICIES

### COMPLIANCE WITH STANDARDS AND LEGISLATION

The consolidated financial statements have been prepared in accordance with IFRS published by the International Accounting Standards Board (IASB) such as they have been adopted by the EU. Furthermore, recommendation RFR1 of the Swedish Financial Reporting Board, "Supplementary Accounting Rules for Groups", has been applied.

The annual financial statements of the Parent Company have been prepared pursuant to the Swedish Annual Accounts Act (1995:1554) and recommendation RFR 2 of the Swedish Financial Reporting Board, "Accounting for Legal Entities", has been applied. This means that IFRS measurement and disclosure requirements are applied. Deviations are presented in the "Parent Company accounting policies" section.

### MEASUREMENT PRINCIPLES APPLIED IN PRESENTATION OF THE FINANCIAL STATEMENTS

Assets and liabilities are recognized at historical cost.

### FUNCTIONAL CURRENCY AND REPORTING CURRENCY

The Parent Company's functional currency is SEK, which is also the reporting currency for the Parent Company and the Group. This means that the financial statements are presented in SEK. All figures, unless otherwise stated, are rounded off to the nearest thousand.

### ASSUMPTIONS WHEN PRESENTING THE PARENT COMPANY'S AND CONSOLIDATED FINANCIAL STATEMENTS

The presentation of reports pursuant to IFRS requires the use of a number of important estimates for reporting purposes. Furthermore, it is necessary for the company management to make certain assessments when applying the Group's accounting policies. The areas which include a high degree of assessment, which are complex or such areas where assumptions and estimates are of considerable importance for the consolidated financial statements are stated in note 33.

### NEW IFRS STANDARDS AND CHANGED ACCOUNTING PRINCIPLES

During 2018 the Group has implemented IFRS 15 "Revenue from contracts with customers" and IFRS 9 "Financial instruments".

New IFRS standards that have not yet been applied by the Group IFRS 16 "Leases" replaces existing IFRS related to the recognition of leasing agreements as from 2019, such as IAS 17 "Leases" and IFRIC 4 "Determining whether an Agreement Contains a Lease". XVIVO Perfusion will apply this standard from January 1, 2019.

IFRS 16 primarily impacts lessees and the central effect is that all leasing agreements that are today recognized as operational leasing agreements shall be recognized in a way that is similar to current recognition of financial leasing agreements. This means that assets and liabilities need to be recognized for operational leasing agreements, with accompanying recognition of expenses for depreciation and interest – unlike today when there is no recognition of a rented asset and a related liability, and leasing fees are expensed on a straight line basis over the term of the lease. As an operational lessee of offices and cars, XVIVO Perfusion will be impacted by the introduction of IFRS 16. The disclosures in Note 9 regarding operational leasing agreements give an indication of the type and scope of the agreements that currently exist.

### CLASSIFICATION

Non-current assets, long-term liabilities and provisions essentially consist of amounts that are expected to be recovered or paid more than 12 months after closing day. Current assets and current liabilities essentially consist of amounts that are expected to be recovered or paid within 12 months of closing day.

### CONSOLIDATION POLICIES

#### SUBSIDIARIES

The consolidated financial statements include the Parent Company XVIVO Perfusion AB (publ), the wholly-owned American subsidiary XVIVO Perfusion Inc,

the wholly-owned subsidiary XVIVO Perfusion Lund AB (formerly Vivoline Medical AB) and the wholly-owned French subsidiary XVIVO Perfusion SAS which was newly started in 2017.

### CONSOLIDATION POLICIES - GROUP

The acquisition of XVIVO Perfusion Inc. was a so-called common control acquisition where both the purchaser and the object had a common owner with a controlling interest. Assets and liabilities were taken over and recognized in the acquisition analysis at consolidation values. See XVIVO Perfusion's 2012 Annual Report for the acquisition analysis.

The acquisition of Vivoline Medical AB (now XVIVO Perfusion Lund AB) was recognized pursuant to the acquisition method, whereby assets and liabilities are recognized at fair value according to an acquisition analysis. The difference between the cost of the subsidiary's shares and the fair value of the acquired assets, liabilities taken over and contingent liabilities constitutes goodwill on consolidation. The purchase price also includes the fair value of all assets or liabilities that are a consequence of a contingent consideration agreement. Acquisition-related costs are expensed when they arise.

Subsidiaries' financial reporting is included in the consolidated financial statements as from the acquisition date until the date when the controlling interest ceases.

Intra-Group receivables and liabilities, income and expenses, and unrealized profits or losses arising from intra-Group transactions are eliminated in their entirety in the presentation of the consolidated financial statements.

### FOREIGN CURRENCY

Transactions in foreign currency are translated to the functional currency at the exchange rate prevailing on the transaction date. Monetary assets and liabilities denominated in foreign currency are translated to the functional currency at the exchange rate prevailing at closing day. Exchange-rate differences arising on translation are recognized in the income statement. Non-monetary assets and liabilities that are recognized at historical cost are translated at the exchange rate applicable on the transaction date. Non-monetary assets and liabilities that are recognized at fair value are translated to the functional currency at the exchange rate applicable on the date of fair-value measurement. The change in exchange rates is then recognized in the same manner as other changes in value for the asset or liability.

The functional currency is the currency in the primary economic environments in which the companies included in the Group conduct their business. The companies included in the Group are the Parent Company and the subsidiaries. The Parent Company's functional currency, as well as the reporting currency, is SEK. The Group's reporting currency is SEK.

Assets and liabilities in foreign operations, including goodwill and other fair value adjustments arising on consolidation, are translated to SEK at the exchange rate applicable at closing day. Revenue and expenses in foreign operations are translated to SEK at average rates that approximate the foreign exchange rates applicable at each transaction date. Translation differences arising in currency translations of foreign operations are recognized in the statement of total comprehensive income.

The following exchange rates have been applied in these statements:

Currency	Average exchange rate		Closing rate	
	2018	2017	Dec 31, 2018	Dec 31, 2017
USD	8,6921	8,5380	8,9710	8,2322
EUR	10,2567	9,6326	10,2753	9,8497

Source: Sweden's Riksbank

### REVENUE

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). 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; Revenue from sales of goods is recognized in the income statement when significant risks and rewards associated with ownership of the goods have been transferred to the purchaser, which nor-

mally occurs upon delivery.

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 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.

## OPERATING EXPENSES AND FINANCIAL INCOME AND EXPENSES

### LEASING

Leasing is classified in the consolidated financial statements as either financial or operational leasing. All the Group's leasing agreements have been classified and recognized as operational leasing agreements. Operational leasing means that the leasing fee is expensed on a straight line basis over the term of the lease. A financial leasing agreement is a leasing agreement whereby the risks and benefits associated with ownership of an asset are essentially transferred from the lessor to the lessee. An operational leasing agreement is a leasing agreement which is not financial.

#### Lessor

Leasing fees pursuant to operational leasing agreements, including a higher first rental payment but excluding expenses for services such as insurance and maintenance, are recognized as revenue on a straight line basis over the leasing period.

#### Lessee

Leasing fees pursuant to operational leasing agreements, including a higher first rental payment but excluding expenses for services such as insurance and maintenance, are recognized as an expense on a straight line basis over the leasing period.

### FINANCIAL INCOME AND EXPENSES

Financial income and expenses consist of interest income on bank balances and receivables and interest-bearing securities, interest expenses on loans, income from dividends, exchange-rate differences, unrealized and realized profits from financial investments and derivative instruments used in financial operations.

## SEGMENT REPORTING

Operating segments are presented according to a management approach, which means that they are presented in the way they are used in internal reporting. The basis for identification of reportable segments is the internal reporting such as it is reported to and followed up by the chief operating decision maker. The Group has identified the Group's CEO as the chief operating decision maker. Two segments are used in internal reporting to the CEO. For further information, see Note 3.

## 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.

Financial instruments recognized in the balance sheet on the assets side include cash and cash equivalents, trade accounts receivable, other receivables and other long-term holdings of securities. On the liabilities side there are accounts payable and other liabilities.

A financial asset or a financial liability is recognized in the balance sheet when the company becomes a party to the contractual provisions of the instrument. Trade accounts receivable are recognized in the balance sheet when an invoice has been sent. Accounts payable are recognized when an invoice has been received. A financial asset is removed from the balance sheet when the contractual rights are realized or expire or when the company loses control over them. The same applies to part of a financial asset. A financial liability is removed from the balance sheet when the contractual obligation is fulfilled or in some other way expires. The same applies to part of a financial liability. At each reporting date, the Group evaluates whether there is objective evidence that there is an impairment requirement for a financial asset or group of assets. Objective evidence comprises observable events that have occurred and which have a negative impact on the ability to

recover the cost of acquisition as well as a considerable or extensive decline in the fair value of a financial investment classified as a financial asset that can be sold.

Receivables and liabilities in foreign currency are measured at the closing day exchange rate. Exchange-rate differences for operating receivables and operating liabilities are included in operating income while exchange-rate differences for financial receivables and liabilities are included in financial income and expenses.

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 impairment model applies on financial assets measured at amortized cost or at fair value through the other comprehensive income, except on investments in equity instruments. A new model for bad debt provision based on the IFRS 9 methodology was implemented in 2018. This did not result in an increased need for write offs due to expected future credit losses.

## TRADE ACCOUNTS RECEIVABLE AND OTHER RECEIVABLES

These types of receivables are stated at amortized cost. Where the duration of the receivables is short, they are recognized at nominal value with no discounting pursuant to the amortized cost method. If the expected holding period is longer than 12 months they are long-term receivables and if it is shorter they are other receivables. Trade accounts receivable are initially measured at fair value and subsequently at amortized cost. When the expected duration of trade receivables is short, they are recognized at nominal value with no discounting. A deduction is made for doubtful receivables, which are assessed individually. Impairment of trade accounts receivable is recognized in operating expenses.

## CASH AND CASH EQUIVALENTS

Cash and cash equivalents comprise cash in hand, immediately available bank balances and other money market instruments with an original duration of less than three months. Fixed interest items are measured at amortized cost.

## ACCOUNTS PAYABLE

Accounts payable are initially recognized at fair value and subsequently at amortized cost by applying the effective interest method.

## INTANGIBLE FIXED ASSETS

The items recognized in the consolidated balance sheet are goodwill, capitalized development expenditure, patents, licenses and trademarks.

### GOODWILL

Goodwill represents the difference between the cost of a business combination and the consolidated value of acquired assets, liabilities taken over and contingent liabilities. Goodwill is measured at the cost of acquisition minus any accumulated write-downs. Goodwill is allocated to a cash-generating unit and is not amortized, pursuant to IFRS, but is tested annually for any impairment requirement.

### CAPITALIZED DEVELOPMENT EXPENDITURE

By research costs is meant expenditure for research with the aim of gaining new scientific or technical knowledge. By development expenditure is meant expenditure where research results or other knowledge are applied to achieve new or improved products or processes.

Expenditure for research is expensed in the period when it arises. In the Group, development expenditure is recognized as an intangible asset if it is assessed that the asset is able to generate future financial rewards and then only provided that it is technically and financially possible to complete the asset, the aim is and it is possible that the asset can be used in the business or sold, and the value can be estimated in a reliable way.

Capitalized development expenditure is recognized in the Group's balance sheet at cost minus accumulated amortization and write-downs.

## ADDITIONAL EXPENSES

Additional expenses for an intangible asset are added to cost only if they increase the future financial rewards that exceed the original assessment and the expenses can be estimated in a reliable manner. All other expenses are expensed when they arise.

### AMORTIZATION

Straight-line amortization is applied in the income statement over intangible assets' estimated useful life, unless the useful life is indefinite. Goodwill is tested for any impairment requirement annually or as soon as there are indications that the asset in question has decreased in value pursuant to IFRS. Intangible assets that can be amortized are amortized from the date when they are available for use. The estimated useful life of the assets is as follows:

Capitalized development expenditure	5-10 years
Patents	10 years
Trademarks	10 years

## PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment is recognized as an asset in the balance sheet if it is probable that future financial rewards will accrue to the company and the cost of the asset can be estimated in a reliable manner. All tangible fixed assets are booked at cost, with a deduction for depreciation. Cost includes expenses that are directly attributable to acquisition of the asset. Additional expenses are added to the carrying amount of the asset or are recognized as a separate asset, depending on which is appropriate, only when it is probable that the future financial rewards associated with the asset will accrue to the Group and the cost of the asset can be measured in a reliable manner. All other forms of repairs and maintenance are recognized as expenses in the income statement when they arise.

### DEPRECIATION OF PROPERTY, PLANT AND EQUIPMENT

Depreciation according to plan of property, plant and equipment is based on a determined useful life. Straight-line depreciation is applied over the assets' estimated useful life and taking residual value into account. The estimated useful life of the assets is as follows:

Plant and machinery	10 years
Equipment, tools, fixtures and fittings	5 years
Computer equipment	3 years
Cars and means of transport	5 years

Assessment of an asset's residual value and useful life is performed annually.

Assets' residual value and useful life are tested each closing day and adjusted when necessary. An asset's carrying amount is immediately depreciated down to its recoverable amount if the asset's carrying amount exceeds its estimated recoverable amount. Profit or loss that arises when divesting or disposing of property, plant and equipment comprises the difference between the sales price and the carrying amount with a deduction for direct selling expenses. The item is recognized as other operating revenues or as other operating expenses in the income statement.

## INVENTORIES

Inventories are recognized as cost or net realizable value, whichever is the lower. The risk of obsolescence is taken into account, and this is assessed on an individual basis. Cost is estimated in accordance with weighted average prices. The cost of in-house produced semi-finished products and finished products consists of direct manufacturing costs and a reasonable share of indirect manufacturing costs based on normal capacity.

## WRITE-DOWNS

Each time a report is to be published, an assessment is made as to whether there is any indication of a decrease in the value of the Group's tangible and intangible assets. Any impairment requirement regarding goodwill and other intangible assets not amortized on an ongoing basis is tested annually or more often if there are indications that the asset may have decreased in value. If this is the case, the Group makes an assessment of the asset's recoverable amount. The recoverable amount is either the asset's fair value, with a deduction for selling expenses, or the value in use, whichever is the higher. By the value in use is meant the present value of all payments received and made which are attributable to the asset during the period it is expected to be used in the business, with the addition of the present value of the net realizable value at the end of the useful life of the asset.

If the estimated recoverable amount is less than the carrying amount, the asset is written down to its recoverable amount. A previous write-down is reversed when there has been a change in the assumptions on the basis of which the asset's recoverable amount was determined when it was written down and consequently the write-down is no longer assessed to be required. Reversals of previously performed write-downs are tested individually and are recognized in the income statement. Write-downs of goodwill are not reversed in a subsequent period.

## EARNINGS PER SHARE

Calculation of earnings per share is based on the Group's net income for the year attributable to the Parent Company shareholders and on the weighted average number of shares outstanding during the year. Potential ordinary shares are only seen as diluting in periods when they lead to a lower profit or a greater loss per share.

## PENSIONS

All employees' pension plans are defined contribution plans. The premiums are expensed on an ongoing basis and there are no commitments to pay further fees. Expenses are charged against income in the Group as and when benefits are earned. For further information, see Note 6.

## PROVISIONS

Provisions are recognized in the balance sheet when XVIVO Perfusion has a legal or informal commitment as a consequence of an event that has occurred and when it is likely that an outflow of resources is required to settle the commitment. Furthermore, it shall be possible to make a reliable estimate of the amount. Provisions are recognized in the amount that corresponds to the best estimate of the payment required to settle the commitment. When it is assessed that the outflow of resources is a long time in the future, the expected future cash flow is

discounted, and the provision is recognized at present value. The discount rate corresponds to the market rate before tax and the risks related to the liability.

## SHAREHOLDERS' EQUITY

Transaction costs that are directly attributable to an issue of new shares or warrants are recognized, net after tax, in shareholders' equity as a deduction from the funds raised through the share issue.

## WARRANTS PROGRAMS

Share-based incentive programs are recognized pursuant to IFRS 2. There are two outstanding warrants programs directed at the company's employees. Employees who have wished to participate in a warrants program have paid a premium corresponding to the market value of the warrant calculated pursuant to Black & Scholes' formula. As the market value has been paid, there is no effect on the company's net income for the period or on its financial position. A description of the warrants programs is to be found in Note 23.

## INCOME TAXES

The current tax expense is calculated on the basis of the tax rules that are in force at closing day or de facto in force in countries where the Parent Company and the subsidiary operate and generate taxable revenues. Management regularly evaluates claims made in tax returns regarding situations where applicable tax rules are subject to interpretation and, when it is assessed appropriate, provisions are made for amounts that will probably be paid to the tax authority.

Deferred tax is stated in its entirety, pursuant to the balance sheet method, for all temporary differences that arise between the taxable value of assets and liabilities and their carrying amounts in the consolidated accounts. Deferred income tax is estimated by applying tax rates (and laws) which are in force or will be in force at closing day and which are expected to apply when the relevant deferred tax asset is realized or the deferred tax liability is settled.

Deferred tax is estimated for temporary differences that arise in participations in subsidiaries, except where the time for reversal of the temporary difference can be controlled by the Group and it is likely that the temporary difference will not be reversed in the foreseeable future.

Total tax is current tax and deferred tax.

Taxes are stated in the income statement except when the underlying transaction is stated in Other comprehensive income, in which case the accompanying tax effect is stated in Other comprehensive income. Current tax is tax that is to be paid or received regarding the current year. This also includes adjustment of current tax attributable to earlier periods. Deferred tax is estimated in accordance with the balance sheet method on the basis of temporary differences between recognized and taxable values for assets and liabilities. The amounts are estimated on the basis of how the temporary differences are expected to be settled and by applying the tax rates and tax rules that are in force or will be in force at closing day. Temporary differences are not taken into consideration in consolidated goodwill and normally not in differences attributable to participations in subsidiaries which are not expected to be taxed in the foreseeable future. In the consolidated accounts untaxed reserves are divided up into a deferred tax liability and shareholders' equity.

Deferred tax assets regarding tax deductible temporary differences and tax loss carry forward are recognized only to the extent that it is likely that these will entail lower tax payments in the future.

## CONTINGENT LIABILITIES

A contingent liability is recognized when there is a possible commitment stemming from events that have occurred and whose occurrence is confirmed only by one or more uncertain future events or when there is a commitment which is not recognized as a liability or provision due to the fact that it is not likely that an outflow of resources will be required.

## PARENT COMPANY'S ACCOUNTING POLICIES

The Parent Company has prepared its annual financial statements pursuant to the Swedish Annual Accounts Act (1995:1554) and recommendation RFR 2 of the Swedish Financial Reporting Board, "Accounting for Legal Entities". The pronouncements that the Swedish Financial Reporting Board has published regarding listed companies have also been applied. Under RFR2 the Parent Company shall apply in the annual financial statements for the legal entity all the IFRS and pronouncements adopted by the EU as far as is possible within the framework of the Swedish Annual Accounts Act and the Pension Obligations Vesting Act and taking into account the connection between accounting and taxation. The recommendation states which exceptions and additions shall be made in respect of IFRS.

### DIFFERENCES BETWEEN THE GROUP'S AND THE PARENT COMPANY'S ACCOUNTING POLICIES

The differences between the Group's and the Parent Company's accounting policies can be seen from the following. The accounting principles stated below for the Parent Company have been applied consistently in all periods presented in the Parent Company's financial reports.

## CLASSIFICATION AND FORMAT

The term income statement is used for the Parent Company while for the Group the term statement of net income is used. Furthermore, the term balance sheet is used for the Parent Company whereas for the Group the term statement of financial position is used. The Parent Company income statement and balance sheet follow the format stipulated in the Swedish Annual Accounts Act, while the statement of total comprehensive income, changes in shareholders' equity and the cash flow statement are based on IAS 1 "Presentation of Financial Statements" and IAS 7 "Statement of Cash Flows". The differences in the Parent Company's income statement and balance sheet compared to the Group's financial statements primarily concern shareholders' equity and the occurrence of provisions as a heading of its own in the balance sheet.

## SUBSIDIARIES

Participations in subsidiaries are recognized in accordance with the cost method. This means that transaction expenses are included in the carrying amount for holdings in subsidiaries. In the consolidated financial statements transaction expenses attributable to subsidiaries are recognized directly in the statement of net income when they arise. Testing of the value of subsidiaries is carried out when there is an indication of a decrease in value.

## INCOME TAXES

In the Parent Company, untaxed reserves are recognized including a deferred tax liability. In the consolidated accounts, however, untaxed reserves are divided up into a deferred tax liability and shareholders' equity.

## NOTE 2. NET SALES

### DISTRIBUTION OF NET SALES

	Group		Parent Company	
	2018	2017	2018	2017
Sales of non-durable goods	164 412	134 639	142 579	114 398
Revenues from sales and leasing of durable goods	15 175	7 348	6 475	6 934
Revenues from freight, service and other sales	8 281	6 355	3 277	2 013
Total	187 868	148 342	152 332	123 345

The Group had no customer during 2018 and 2017 that constituted more than 10% of total sales.

It has been assessed that revenues have come from similar products and services.

## GEOGRAPHIC AREAS

	Group			
	Revenues from external customers		Non-current assets	
	2018	2017	2018	2017
Sweden	1 982	2 500	318 191	254 672
Americas	121 521	87 947	6 357	3 780
EMEA excluding Sweden	54 881	49 021	-	-
Asia/Pacific	9 484	8 874	-	-
Total	187 868	148 342	324 548	258 452

Revenues from external customers have been allocated to individual countries according to the country sales were made to. Non-current assets refer to all of the Group's intangible non-current assets and property, plant and equipment.

## NOTE 3. SEGMENTS

The Group's business is divided up into segments on the basis of what parts of the business the company's chief operating decision maker follows up, a so-called "management approach".

The Group's business is organized so that Group management follows up sales and the gross income that the Group's various revenue flows generate. As Group management follows up the sales and gross margin of the business and makes decisions regarding the distribution of resources on the basis of the goods the Group develops and sells, these constitute the Group's segments.

The Group's internal reporting is thus constructed so that Group management can follow up all goods' performance. It is on the basis of this internal reporting that the Group's segments have been identified, as the various parts have undergone a process that has aimed at combining segments that are similar. This means that segments have been combined when they have similar financial characteristics, such as similar gross margins and sales trends.

The following segments have been identified:

- Durable goods: sales and leasing revenues from XPS and LS.
- All non-durable goods: revenue flows from sales of goods and services that are not durable goods.

## GROUP SEGMENTS

	All revenue except durable goods		Durable goods		Consolidated total	
	2018	2017	2018	2017	2018	2017
Revenues from external customers	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
Gross income	133 288	110 632	2 665	2 764	135 953	113 396

The segments' gross margin includes directly attributable items and items that can be divided up into segments in a reasonable and reliable manner. The items recognized in the segments' gross income are measured in accordance with the gross margin that Group management follows up.

## NOTE 4. OTHER OPERATING REVENUES

	Group		Parent Company	
	2018	2017	2018	2017
Exchange-rate gains	1 281	864	1 270	833
Other revenues	-	106	173	167
Total	1 281	970	1 443	1 000

## NOTE 5. OTHER OPERATING EXPENSES

	Group		Parent Company	
	2018	2017	2018	2017
Exchange-rate losses	-761	-1 057	-718	-1 006
Other intra-Group services	-	-	-334	-950
Depreciation of durable goods	-4 075	-2 987	-3 034	-2 943
Total	-4 836	-4 044	-4 086	-4 899

## NOTE 6. EMPLOYEES, EMPLOYEE BENEFIT EXPENSES AND BOARD FEES

### AVERAGE NUMBER OF EMPLOYEES

	Total		Whereof men	
	2018	2017	2018	2017
Parent Company, Sweden	13	11	5	4
Subsidiary, Sweden	8	5	6	3
Subsidiary, USA	13	12	9	9
Subsidiary, France	1	1	-	-
Total	35	29	15	16

### PERCENTAGE OF WOMEN IN SENIOR POSITIONS

	2018	2017
<b>Group</b>		
Board	33 %	17 %
Senior management	17 %	33 %

### EMPLOYEE BENEFIT EXPENSES

Group	2018	2017
Salary and other remuneration	46 167	36 350
Pension expenses, defined contribution plans	2 982	3 916
Social security contributions	8 335	7 306
Total	57 484	47 572

Parent Company	2018	2017
Salary and other remuneration	12 926	13 119
Pension expenses, defined contribution plans	1 835	2 936
Social security contributions	4 308	4 300
Total	19 069	20 355

## SALARY AND OTHER REMUNERATION DIVIDED UP BETWEEN BOARD MEMBERS/CEO AND OTHER EMPLOYEES

	Board/CEO		Other employees	
	2018	2017	2018	2017
Parent Company	1 143	3 638	12 945	9 482
- of which bonus payments and similar remuneration	(- 125)	(125)	(1 620)	(1 196)
Subsidiaries	8 640	4 632	24 023	18 599
- of which bonus payments and similar remuneration	(2 913)	(2 154)	(4 569)	(1 955)
Total	9 783	8 269	36 968	28 080
- of which bonus payments and similar remuneration	(2 913)	(2 279)	(6 189)	(3 151)

### BOARD MEMBERS

Board fees of SEK 1 000 thousand (850) were paid during the year, in accordance with the resolution adopted at the 2017 Annual General Meeting. SEK 195 thousand (170) was paid to Chairman of the Board and SEK 125 thousand (100) to each of the other Board members, as well as SEK 40 thousand to the Chairman of the Audit Committee, SEK 40 thousand to the Chairman of the Remuneration Committee and SEK 25 thousand to each of the other members of these committees. There are no pension expenses or pension obligations for the Board members.

At the Annual General Meeting held on April 27, 2018 in Gothenburg a resolution was adopted that Board fees totaling SEK 1 035 thousand (1 000) shall be paid up until the next Annual General Meeting. SEK 205 thousand (195) will be paid to Chairman of the Board and SEK 130 thousand (125) to each of the other Board members, as well as SEK 40 thousand (40) to the Chairman of the Audit Committee, SEK 40 thousand (40) to the Chairman of the Remuneration Committee and SEK 25 thousand (25) to each of the other members of these committees.

### CEO

Magnus Nilsson, the CEO, was paid remuneration totaling SEK 8 666 thousand (6 177) during the 2018 financial year, including a vacation allowance and other benefits, of which SEK 2 651 thousand (2 279) was variable remuneration. No car allowance was paid to the CEO. As long as the CEO is based in Sweden, his pension follows a defined contribution plan and pension premiums of 35% of his salary are paid by the company. Some of the pension premiums are paid to endowment insurance owned by the company, as described below. Since the CEO worked in the US during 2018, no pension payments were made. As compensation, the CEO was paid a corresponding amount, SEK 1 560 thousand, as salary. If the company terminates the CEO's employment, notice of 6 months shall be given. Similarly, if the CEO resigns, he must give notice of 6 months. If the company terminates the CEO's employment, separation pay of 12 months' salary shall be paid. The CEO's retirement age is 65. His employment is regulated by a CEO agreement.

### OTHER SENIOR EXECUTIVES

Salary of SEK 7 584 thousand (7 505) was paid during the 2018 financial year to senior executives, the Group's management team of 5 (5) people excluding the CEO, including a vacation allowance, of which SEK 1 800 thousand (1 445) was variable remuneration. The variable remuneration is based on the outcome of various parameters compared with set objectives. The parameters relate to the company's sales and results as well as individually set objectives. Premiums for normal occupational pension were paid. The retirement age is 65 for these senior executives. If the company terminates the senior executives' employment, notice of 3-6 months shall be given. Similarly, if the senior executives resign, they must give notice of 3-6 months. No-one is entitled to separation pay. There are no loans to senior executives.

### DEFINED CONTRIBUTION PENSION PLANS

In Sweden the Group has defined contribution pension plans for employees. The entire cost of these is met by the company. Outside Sweden there are defined contribution plans which are partly paid for by the subsidiaries and are partly covered by fees paid by the employees. Payment for these plans is done on an ongoing basis according to the rules of each individual plan. Of the costs for defined contribution pension plans in 2018, no costs were related to the CEO. Prior year, 2017, SEK 708 thousand was related to the CEO.

### ENDOWMENT INSURANCE

The company has a pension obligation to the CEO that is covered by the outcome of endowment insurance owned by the company. Pursuant to IAS 19, the pension obligation has been classified as a defined contribution pension plan, and thus the endowment insurance and the pension obligation are recognized as a net amount. A total of SEK - thousand (624) was paid for this endowment insurance during the year.

## NOTE 7. AUDITORS' FEES AND REIMBURSEMENT OF COSTS

KPMG	Group		Parent company	
	2018	2017	2018	2017
Auditing	290	305	250	265
Auditing activities in addition to auditing	-	-	-	-
Tax consulting	36	12	36	12
Other services	437	135	437	135
Total	763	452	723	412

Auditing involves review of the Annual Report, of the accounting records, and of the management of the Board of Directors and CEO, and other tasks that the company's auditors are required to undertake, as well as advice and other assistance that arise from observations as a result of this review or the carrying out of these other tasks. Auditing activities in addition to auditing involve quality assurance services, including assistance as a result of such review as shall be carried out in accordance with national statutes, the articles of association, company statutes or agreements and which result in a report intended for other parties than the client. Tax consulting is recognized separately. Anything else is other services.

## NOTE 8. OPERATING EXPENSES DIVIDED UP ACCORDING TO TYPE OF COST

	Group	
	2018	2017
Raw materials and consumables	-23 550	-17 365
Change in inventories of finished goods and products in progress	-12 338	-6 939
Employee benefit expenses	-63 285	-50 934
Depreciation, amortization and impairment	-16 923	-14 917
Other external expenses	-58 291	-50 995
Other operating expenses	-762	-1 056
Total	-175 149	-142 206

## NOTE 9. LEASING FEES FOR OPERATIONAL LEASES

The Group rents office premises and warehouse facilities in Gothenburg. The current rental agreement for office premises expires on December 31, 2023. The rental agreements for warehouse facilities expire on March 31, 2019 with option for extension. The Group also rents office premises in Denver, Colorado. The current rental agreement expires on August 1, 2019 with an option for extension. The Group also rents office and warehouse premises in Lund. The current rental agreement expires on October 31, 2019 with option for extension. All rental agreements are classified as operational leasing agreements.

Rental fees are linked to CPI and vary with the market as a whole. Variable fees are invoiced 1:1 in arrears after an annual review. There are no restrictions as a result of leasing agreements already entered into. Where rebuilding or extension work has been paid by the Group, individual testing is carried out to ascertain whether the costs can be included in the balance sheet or whether they are to be expensed in their entirety.

The Group has entered into leasing agreements for two company cars and some office equipment.

Minimum future leasing fees payable pursuant to non-reversible contracts are distributed as follows:

	Group		Parent Company	
	2018	2017	2018	2017
Within one year	3 235	3 547	1 476	1 567
Within two to five years	5 265	1 351	4 038	399
Later than five years	-	-	-	-
Total	8 500	4 898	5 514	1 966

Fees expensed for operational leasing agreements are as follows:

	Group		Parent Company	
	2018	2017	2018	2017
Minimum leasing fees	3 609	3 502	1 654	1 977
Total leasing expenses	3 609	3 502	1 654	1 977

The Group leases out machines for lung perfusion pursuant to operational leasing agreements. Future non-reversible leasing payments are as follows:

	Group		Parent Company	
	2018	2017	2018	2017
Within one year	2 144	3 473	2 144	2 413
Between one and five years	2 124	4 522	2 124	2 793
Later than five years	-	-	-	-
Total	4 268	7 994	4 268	5 206

## NOTE 10. NET FINANCIAL INCOME

	Group		Parent Company	
	2018	2017	2018	2017
Interest income	449	-	1 288	687
Exchange-rate gains	3 803	1 489	6 236	3 583
Financial income	4 252	1 489	7 524	4 270
Interest expenses	-128	-108	-110	-88
Exchange-rate losses	-540	-1 008	-885	-5 045
Impairment, non-realized loss, endowment insurance	-86	-27	-69	-27
Financial expenses	-754	-1 143	-1 064	-5 160
Total	3 498	346	6 460	-890

## NOTE 11. EXCHANGE-RATE DIFFERENCES

	Group		Parent Company	
	2018	2017	2018	2017
In operating income	555	-192	552	-172
In financial items	3 263	-481	5350	-1 462
Total	3 818	-673	5 902	-1 634

## NOTE 12. YEAR-END ADJUSTMENTS

	Parent company	
	2018	2017
Change in tax allocation reserve	-1 237	-700
Group contribution paid	-18 300	-3 200
Total	-19 537	-3 900

## NOTE 13. INCOME TAXES

### RECOGNIZED IN STATEMENT OF TOTAL COMPREHENSIVE INCOME AND INCOME STATEMENT

	Group		Parent Company	
	2018	2017	2018	2017
<b>Current tax expense (-)</b>				
Tax expense for the year	-2 816	-3 903	-2 367	-2 544
Adjustment of tax pertaining to previous years	122	-248	-	-55
Total current tax expense	-2 694	-4 151	-2 367	-2 599

### Deferred tax on temporary differences

Deferred tax in taxable value capitalized/utilized during the year in loss carry-forwards	968	1 718	-120	113
Effects from changed income tax rates	-2 474	1 241	-	-
Total deferred tax expense	-613	-	-	-
Total tax expense recognized	-2 119	2 959	-120	113
Total redovisat skattekostnad	-4 813	-1 192	-2 487	-2 486

	Group		Parent Company	
	2018	2017	2018	2017
<b>Reconciliation effective tax rate</b>				
Income before tax	17 497	7 453	10 285	10 328
Tax pursuant to current tax rate for Parent Company (22 %)	-3 849	-1 640	-2 263	-2 272
Difference in foreign tax rates	5	-383	-	-
Non-deductible expenses	-356	-229	-102	-207
Non-taxable income	5	-	5	-
Tax effect of standard interest rate on tax allocation reserve	-7	-7	-7	-7
Utilization of previously non-capitalized loss carry-forwards	-	73	-	55
Capitalized loss carry-forwards from previous years	-	1 241	-	-
Effects from changed income tax rates	-733	-	-120	-
Difference in recorded and paid tax previous year	122	-247	-	-55
Total tax expense	-4 813	-1 192	-2 487	-2 486

### TAX ATTRIBUTABLE TO OTHER COMPREHENSIVE INCOME

	Group		Parent Company	
	2018	2017	2018	2017
	Before tax	After tax	Before tax	After tax
Translation differences for the year after translation of foreign businesses	2 783	-	2 783	-3 078
Translation differences for the year after translation of foreign businesses (extended investment)	2 092	-473	1 619	-2 109
Other comprehensive income	4 875	-473	4 402	-5 187

	Parent company		2017	
	2018	2017	Before tax	After tax
	Before tax	After tax	Before tax	After tax
Translation differences for the year after translation of foreign businesses	-	-	-	-
Other comprehensive income	-	-	-	-

### RECOGNIZED DIRECTLY IN SHAREHOLDERS' EQUITY

	Group		Parent Company	
	2018	2017	2018	2017
<b>Tax items recognized directly in shareholders' equity</b>				
<b>Tax expense (-)</b>				
Current tax related to transaction expenses for new share issue	-	2 039	-	2 039
Total tax items recognized directly in shareholders' equity	-	2 039	-	2 039

### RECOGNIZED IN STATEMENT OF FINANCIAL POSITION AND BALANCE SHEET

	Group		Parent Company	
	2018	2017	2018	2017
<b>Deferred tax asset</b>				
Deferred tax related to internal profit on inventories	4 375	3 100	-	-
Deferred tax related to pensions and similar obligations	1 402	1 522	1 402	1 522
Deferred tax related to capitalized loss carry-forwards	7 771	10 773	-	-
Total deferred tax asset	13 548	15 395	1 402	1 522
<b>Deferred tax liability</b>				
Deferred tax, tax allocation reserve	2 233	1 961	-	-
Total deferred tax liability	2 233	1 961	-	-

## NOTE 14. INTANGIBLE NON-CURRENT ASSETS

	Group		Parent Company	
	2018	2017	2018	2017
<b>Capitalized development expenditure</b>				
Opening acquisition cost	219 202	191 057	143 039	114 895
Business combination	47 188	28 144	47 188	28 144
Capitalized expenditure for the year	266 390	219 202	190 227	143 039
Opening amortization	-45 772	-35 889	-33 642	-23 759
Business combination	-10 158	-9 883	-10 158	-9 883
Amortization for the year	-55 930	-45 772	-43 800	-33 642
Closing accumulated amortization	210 460	173 430	146 427	109 397
<b>Patents, licenses and trademarks</b>				
Opening acquisition cost	6 627	5 461	3 890	2 966
Business combination	855	1 166	855	924
Capitalized expenditure for the year	7 482	6 627	4 745	3 890
Opening amortization	-3 155	-2 495	-1 590	-1 213
Correction of error in opening balances	-703	-659	-429	-377
Business combination	-3 858	-3 155	-2 019	-1 590
Amortization for the year	3 624	3 472	2 726	2 300
<b>Goodwill</b>				
Opening acquisition cost	65 273	65 672	-	-
Exchange-rate differences for the year	341	-399	-	-
Closing accumulated acquisition cost	65 614	65 273	-	-
Closing carrying amount	65 614	65 273	-	-

### Amortization has been divided up per function in the income statement as follows:

Cost of goods sold	-	-	-	-
Selling expenses	-	-	-	-
Administrative expenses	-	-	-	-
Research and development costs	-10 861	-10 542	-10 587	-10 260
Other operating expenses	-	-	-	-
Total	-10 861	-10 542	-10 587	-10 260

The Group's goodwill is attributable to acquisitions of subsidiaries and their businesses. The Perfadex sales business is in its entirety considered as a cash-generating unit in impairment testing.

Goodwill has been tested for impairment on the basis of budgets and forecasts, where the first year of the forecast is based on the company's budget and the subsequent four years on the basis of the historical growth rate adjusted by the company management's forecasts for the future. The forecasts have been produced internally by the company management on the basis of historical data, management's cumulative experience and their best assessment of the company's development potential and market growth. Cash flows forecast after five years have been based on a growth rate of 6.0% per year. The forecast cash flows have been subjected to present value computation, using a discount rate of 9.7 percent before tax. The most important variables in the forecast are market share and market growth, the gross margin, selling expenses and capital expenditure. The calculation is based on a continuing good gross margin and the need for capital expenditure to replace existing assets has been assessed to be relatively low. It is assumed that working capital changes proportionate to sales and the debt/equity ratio is assessed to be unchanged as it has been assumed that growth will be within the framework of the existing business and using company funds. The recoverable amount, which in the Group is calculated as the value in use, is greater than the carrying amount. In the assessment of company management, no conceivable changes in the important variables and assumptions lead to the unit's recoverable amount being lower than the carrying amounts.

In order to support the impairment testing of goodwill that has been carried out, a comprehensive analysis has been made of the sensitivity of the variables used in the model. An assumed increase in the discount rate to 15 percent demonstrates that the recoverable amounts are still greater than the carrying amounts. Other assumptions, such as the gross margin, capital expenditure requirements and the growth rate, have been assumed to be constant. Conceivable changes in these assumptions over time are not expected to lead to any indication that the carrying amount for goodwill cannot be defended.

## NOTE 15. PROPERTY, PLANT AND EQUIPMENT

	Group		Parent Company	
	2018	2017	2018	2017
<b>Machinery, equipment, fixtures and fittings</b>				
Opening acquisition cost	27 923	22 847	17 219	15 095
Acquisitions for the year	6 663	5 624	710	2 272
Sales/disposals for the year	-2 173	-300	-1 767	-148
Exchange-rate differences for the year	459	-248	-	-
Closing accumulated acquisition cost	32 872	27 923	16 160	17 219
Opening depreciation	-11 646	-7 681	-6 506	-3 594
Sales/disposals for the year	629	300	1 179	148
Depreciation for the year	-6 063	-4 379	-3 466	-3 060
Exchange-rate differences for the year	-177	114	-	-
Closing accumulated depreciation	-17 257	-11 646	-8 793	-6 506
Closing carrying amount	15 615	16 277	7 367	10 713

### Depreciation has been divided up per function in the income statement as follows:

Cost of goods sold	-528	-385	-	-
Selling expenses	-37	-	-	-
Administrative expenses	-1 384	-985	-433	-1 116
Research and development costs	-39	-17	-	-
Other operating expenses	-4 075	-2 992	-3 033	-2 944
Total	-6 063	-4 378	-3 466	-3 060

## NOTE 16. PARTICIPATIONS IN GROUP COMPANIES

	Parent company	
	2018	2017
Opening acquisition cost	161 174	160 182
Acquisitions for the year	-	992
Closing carrying amount	161 174	161 174

### COMPANIES OWNED BY XVIVO PERFUSION AB (PUBL):

	Book value			
	Share in %	2018	2017	
Company	Corp. no.	Residence	No. of shares	
XVIVO Perfusion Inc.	45-5472070	Denver, USA	1 000	100
XVIVO Perfusion Lund AB	556761-1701	Lund, Sverige	11 402 818	100
XVIVO Perfusion SAS	531 229 219	Lyon, Frankrike	5 000	100
Total				161 174

## NOTE 17. INVENTORIES

	Group		Parent Company	
	2018	2017	2018	2017
Raw materials and consumables	16 321	15 609	6 024	3 741
Work in progress	527	1 547	-	-
Finished goods and goods for resale	19 539	13 548	7 671	3 563
Total	36 387	30 703	13 695	7 304

The Group's closing inventories include impairment of SEK 665 thousand (332) for obsolescence of inventories.

## NOTE 18. RECEIVABLES FROM AND LIABILITIES TO GROUP COMPANIES

The Parent Company has net receivables from the subsidiary XVIVO Perfusion Inc. in the amount of SEK 37 575 thousand (39 217), net liabilities to the subsidiary XVIVO Perfusion Lund AB in the amount of SEK 19 386 (6 852) and net liabilities to the subsidiary XVIVO Perfusion SAS in the amount of SEK 804 thousand (879).

## NOTE 19. TRADE ACCOUNTS RECEIVABLE

Trade accounts receivable are recognized after bad debt losses that have arisen during the year have been taken into account. Recorded bad debt losses in the Group for 2018 amounted to SEK - thousand (157), of which SEK - thousand (-) was in the Parent Company. Reserved bad debt losses in the Group for which provisions were made during the year amount to SEK 319 thousand (377), of which SEK 175 thousand (233) was in the Parent Company.

	Group		Parent Company	
	2018	2017	2018	2017
Accounts receivable - trade	44 034	25 374	17 762	12 338
Minus provisions for doubtful receivables	-319	-377	-175	-233
Total	43 716	24 997	17 587	12 105

### Age structure – trade accounts receivable

Not due	29 338	16 150	9 687	8 218
Due 0-30 days ago	4 284	5 057	1 640	1 784
Due 31-90 days ago	5 510	2 083	3 414	584
Due 91-180 days ago	3 628	1 033	1 958	922
Due >180 days ago	1 274	1 051	1 063	830
Total	44 034	25 374	17 752	12 338

## NOTE 20. PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent Company	
	2018	2017	2018	2017
Rent and other property costs	427	302	348	302
Prepaid insurance	2 545	2 797	2 080	2 447
Other prepaid expenses	4 332	4 726	2 766	4 201
Total	7 304	7 825	5 194	6 950

## NOTE 21. CASH, CASH EQUIVALENTS AND BANK OVERDRAFT FACILITY

Cash and cash equivalents in the cash flow statement consist of the following sub-components:

	Group		Parent Company	
	2018	2017	2018	2017
Cash and bank balances	187 064	195 322	178 248	173 421
Total	187 064	195 322	178 248	173 421

There were no short-term investments.

Cash and cash equivalents include bank balances frozen as security for bank guarantees of SEK 0.8 million (0.3) in both the Parent Company and the Group.

A bank overdraft facility was utilized in the amount of SEK 0 million (0) in the Group and SEK 0 million (0) in the Parent Company. The bank overdraft facility granted is in the amount of SEK 30 million (30) in the Group and SEK 30 million (20) in the Parent Company.

## NOTE 22. SHAREHOLDERS' EQUITY

### SHARE CAPITAL

There is only one class of shares and all shares carry the same rights. At December 31, 2018 the registered share capital comprised 26,402,496 shares (26,190,496).

### OTHER CAPITAL PROVIDED

This is equity contributed by shareholders.

### RESERVES

Reserves consist of a statutory reserve in the Parent Company and translation reserves including all exchange-rate differences that arise when translating financial reports from foreign businesses that have prepared their financial reports in another currency than the currency that the Group's financial reports are presented in. The Parent Company and the Group present their financial reports in SEK.

## ACCUMULATED EXCHANGE-RATE DIFFERENCE IN SHAREHOLDERS' EQUITY

	Group	
	2018	2017
Opening value	8 618	13 341
Exchange-rate difference for the year in foreign subsidiaries, net after tax	4 403	-4 723
Total	13 021	8 618

The disclosure requirement pursuant to chapter 5 § 14 of the Swedish Annual Accounts Act regarding specification of a change in shareholders' equity compared with the previous year's balance sheet is presented in the report "Changes in shareholders' equity".

### RETAINED EARNINGS INCLUDING NET INCOME FOR THE YEAR

Retained earnings including net income for the year include profits earned in the Parent Company and its subsidiaries.

### RESTRICTED RESERVES

Restricted reserves in the Parent Company may not be reduced by the distribution of profits.

#### Statutory reserve

The purpose of the statutory reserve has been to save part of net profits. These are not to be used to cover an accumulated loss.

#### Development expenditure reserve

The amount capitalized regarding development expenditure shall be transferred from non-restricted equity to a development expenditure reserve in restricted equity. The reserve shall be reduced as and when the capitalized expenditure is amortized or written down. It is managed in a similar way to a revaluation reserve.

### NON-RESTRICTED EQUITY

Retained earnings in the Parent Company, that is the previous year's retained earnings and income minus dividend paid during the year, together with net income for the year, constitute non-restricted equity, that is the amount that is available for dividend to the shareholders.

XVIVO Perfusion is in an expansion phase and the company's policy is that the company's profits are best used to finance continued development and expansion of the business rather than as dividend to the shareholders.

## NOTE 23. EARNINGS PER SHARE

Calculations have been made in accordance with IAS 33 Earnings per share. Earnings per share are based on net income for the year in the Group attributable to the Parent Company's shareholders divided by the weighted average number of shares outstanding during the year.

Earnings per share	2018	2017
Consolidated net income for the year	12 685	6 260
Weighted average number of shares before dilution	26 302 385	25 440 188
Dilution effect of warrants program	-	253 361
Weighted average number of shares after dilution	26 302 385	25 693 549
Earnings per share before dilution, SEK	0,48	0,25
Earnings per share after dilution, SEK	0,48	0,24

### WARRANTS PROGRAM

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 entitles 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 24. UNTAXED RESERVES

Tax allocation reserves	Parent company	
	2018	2017
Allocation, assessment of tax 2013	-	2 263
Allocation, assessment of tax 2014	1 950	1 950
Allocation, assessment of tax 2015	4 000	4 000
Allocation, assessment of tax 2017	700	700
Allocation, assessment of tax 2018	3 500	-
Total	10 150	8 913

## NOTE 25. ACCRUED EXPENSES AND DEFERRED INCOME

	Group		Parent Company	
	2018	2017	2018	2017
Vacation pay	4 685	3 628	2 735	2 348
Accrued social security contributions	2 284	2 121	1 626	1 479
Accrued special employer's contribution for pension expenses	811	804	479	680
Accrued salary and bonus	4 315	3 521	1 288	1 142
Board fees	1 035	1 000	1 035	1 000
Auditing	290	250	250	250
Other accrued expenses	9 064	7 175	5 208	3 405
Deferred income	1 712	188	473	188
Total	24 196	18 687	13 094	10 942

## NOTE 26. FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT

Through its operations the Group is exposed to various types of financial risk. Financial risk pertains to fluctuations in the company's earnings and cash flow as a result of changes in exchange rates, interest rates and refinancing and credit risks.

### CAPITAL RISK

The Group's aim regarding the capital structure is to secure the Group's ability to continue operations, so that it can continue to generate returns for shareholders and benefits for other stakeholders, and to maintain an optimal capital structure to keep the cost of capital down. The Group can change the dividend to shareholders, repay capital to shareholders, issue new shares, buy back its own shares or sell/buy assets with the aim of maintaining or adjusting the capital structure.

XVIVO Perfusion's Board considers that the Group should have a strong capital base to enable continued high growth, both organic and through acquisitions. The aim is that the Group will be able to meet its financial obligations in good times and bad without significant unforeseen costs and without risking the Group's reputation. Liquidity risks are managed centrally for the entire Group by the Finance Department.

### FINANCIAL POLICY

XVIVO Perfusion has a Group policy for its financial operations, which defines financial risks and states how the company should manage these risks. Furthermore, the policy states which reports must be prepared. Under this policy, the company must always maintain liquidity corresponding to known future net cash outflows over a period of not less than three months.

### AGREEMENT TERMS AND CONDITIONS

Maturity structure of financial liabilities:

	Within 1 year	2 years	3 years	4 years	>4 years	Total
Dec 31, 2017						
Accounts payable	11 121	-	-	-	-	11 121
Other liabilities	19 775	-	-	-	-	19 775
Dec 31, 2017						
Accounts payable	16 333	-	-	-	-	16 333
Other liabilities	26 240	-	-	-	-	26 240

XVIVO Perfusion's total credit facilities amounted to SEK 30 million (30), of which SEK 0 million (0) was utilized.

The company did not have any interest-bearing liabilities during the year. Interest expenses recognized for the year are a maintenance fee for a bank overdraft facility and an interest expense related to a tax account.

### CREDIT RISKS

The Group's financial assets are recognized at SEK 241 million (229), of which SEK 187 million (195) is cash and cash equivalents. Historically, the Group has had low credit losses and this was also true for 2018. Risk is limited through the use of credit assessments and advance payments from new customers, as well as through close customer monitoring by the finance and marketing functions conjunctively. Furthermore, individual testing is performed of accounts receivable in terms of solvency and credit rating at closing day.

### CURRENCY RISKS

Currency risk is the risk of fluctuations in the value of financial instruments due to exchange-rate changes. This risk is related to changes in expected and contracted payment flows (transaction exposure), the revaluation of foreign subsidiaries' assets and liabilities in foreign currencies (translation exposure) and financial exposure in the form of currency risks in payment flows for loans and investments. The company is impacted by variations in exchange rates. The aim is to minimize the impact of these changes wherever practically possible.

Changes in EUR and USD have the greatest impact. External sales from the US subsidiary are entirely in USD. Inflows are matched with the subsidiary's outflows in the form of costs, which are also primarily in USD. External sales from the Swedish Parent Company and the Swedish subsidiary are in EUR, 82 percent (78), AUD, 7 percent (10), SEK, 4 percent (6), and other currencies, namely USD, GBP and CAD, 7 percent (4). Most of the costs for the Swedish units are in SEK, but there are some costs in EUR. These outflows are matched as far as possible with inflows in EUR.

### SENSITIVITY ANALYSIS

In order to manage interest and currency risks, the Group aims to reduce the impact of short-term fluctuations on the Group's results. However, in the long term lasting changes in exchange rates and interest rates will have an impact on the consolidated results.

It has been calculated that a general increase of 4 percent in SEK against all other foreign currencies reduced the Group's operating income before tax by approximately SEK 4 million (3) for the year that ended on December 31, 2018.

## NOTE 27. FAIR VALUE AND CARRYING AMOUNTS OF FINANCIAL ASSETS AND LIABILITIES

### GROUP

Financial assets and liabilities amounted to SEK 234 million (223) and SEK 43 million (31), respectively. There has been no forward cover for the currency components included in the above figures.

### PARENTCOMPANY

Financial assets and liabilities amounted to SEK 238 million (229) and SEK 46 million (28), respectively. There has been no forward cover for the currency components included in the above figures.

	Financial assets measured at amortized cost			
	Group		Parent Company	
	2018	2017	2018	2017
<b>Assets in balance sheet</b>				
Loans and receivables	43 716	24 997	56 694	52 957
Other current receivables	3 209	2 434	3 375	2 711
Cash and cash equivalents	187 064	195 322	178 248	173 421
Total	233 989	222 753	238 317	229 089

	Financial liabilities measured at amortized cost			
	Group		Parent Company	
	2018	2017	2018	2017
<b>Liabilities in balance sheet</b>				
Accounts payable	16 333	11 121	10 212	6 963
Other liabilities	26 240	19 775	35 435	20 559
Total	42 573	30 896	45 647	27 522

All of the Group's assets and liabilities in the balance sheet are measured at amortized cost. The carrying amount is an approximation of the fair value, and these items are thus not divided into levels in accordance with the measurement hierarchy.

## NOTE 28. PLEDGED ASSETS FOR OWN LIABILITIES

	Group		Parent Company	
	2018	2017	2018	2017
Chattel mortgages	30 000	30 000	30 000	27 000
Bank guarantees	762	298	762	298
Total	30 762	30 298	30 762	27 298

## NOTE 29. APPROPRIATION OF NON-RESTRICTED EQUITY

### PROPOSED ALLOCATION OF NON-RESTRICTED EQUITY

Share premium reserve	472 345 968
Retained earnings	-45 939 478
Net income for the year	7 797 711
Earnings at the disposal of the AGM	434 204 201
To be carried forward	434 204 201

## NOTE 30. CASH FLOW STATEMENT

	Group		Parent Company	
	2018	2017	2018	2017
<b>Interest paid and received</b>				
Interest received	449	-	442	687
Interest paid	-132	-108	-115	-88
Total	317	-108	327	599

### Adjustment for non-cash items

Depreciation, amortization and impairment of assets	16 923	14 917	14 053	13 320
Provisions for doubtful trade accounts receivable	144	377	-	233
Inventory obsolescence	665	77	665	-
Capital gain from sales of fixed assets	36	-	-	-
Changes in provisions	-22	114	-22	114
Translation differences/exchange-rate differences	-1 674	-2 302	-875	-104
Total	16 072	13 183	13 821	13 563

## NOTE 31. TRANSACTIONS WITH RELATED PARTIES

### RELATED PARTIES

The Parent Company is closely associated with the subsidiaries XVIVO Perfusion Inc., XVIVO Perfusion Lund AB and XVIVO Perfusion SAS. Of the Parent Company's total revenues and purchases, SEK 84 454 thousand (64 368) are revenues from the subsidiaries and SEK 81 648 thousand (63 338) purchases from the subsidiaries.

Internal pricing within the Group is based on the arm's length principle, that is between parties that are independent of each other, well-informed and with a vested interest in the transactions.

### TRANSACTIONS WITH KEY PERSONS IN SENIOR POSITIONS

The Board members of XVIVO Perfusion did not receive any other remuneration in addition to Board fees during 2017 and 2018, except in one case: the Board member Folke Nilsson invoiced the company SEK 39 Thousand (36) in 2018 for consultancy services in the field of heart transplantation.

Total remuneration paid is presented in Note 6, Employees, employee benefit expenses and Board fees.

## NOTE 33. EVENTS AFTER CLOSING DAY

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

## NOTE 33. CRITICAL ASSESSMENTS AND ESTIMATES

### RECOVERY OF VALUE OF DEVELOPMENT EXPENDITURE

There are no indications of further impairment requirements at December 31, 2018. The projects that have been entered as assets can reasonably be assumed to lead to products that will generate revenues in the near future. For further information, see Note 1, Accounting Policies.

### IMPAIRMENT TESTING OF GOODWILL

When calculating cash-generating units' recoverable amount for the assessment of any impairment requirement for goodwill, several assumptions regarding future conditions and estimates of parameters have been made. An account of these is to be found in Note 14.

### OPERATIONAL LEASING AGREEMENTS

See Note 9 for a description of leasing agreements for office and storage buildings. Due to the fact that the rent that the Group pays to the lessor is regularly adjusted in accordance with market rates and the Group does not own any risk for the building's residual value, it has been assessed that practically all financial risks and benefits associated with the building are owned by the lessor. On the basis of these qualitative factors, the conclusion is drawn that the leasing agreements are operational.

See Note 10 for a description of leasing agreements for XPS and XVIVO LS machines. At December 31, 2018 XVIVO Perfusion had entered into 4 (6) leasing agreements with customers regarding XPS machines and 1 (1) leasing agreement regarding XVIVO LS machines. Due to the fact that XVIVO Perfusion owns all risk regarding the machines' residual value and service requirements, it has been assessed that practically all financial risks and benefits associated with the building are owned by XVIVO Perfusion. On the basis of these qualitative factors, the conclusion is drawn that the leasing agreements are operational.

## NOTE. 34 RECONCILIATION OF ALTERNATIVE PERFORMANCE MEASURES

### EBITDA

SEK thousands	2018	2017
<b>Operating income</b>	<b>14 000</b>	<b>7 106</b>
Amortization and impairment of intangible assets	10 861	10 542
Depreciation and impairment of tangible assets	6 062	4 375
<b>EBITDA (Operating income before depreciation and amortization)</b>	<b>30 923</b>	<b>22 023</b>

### GROSS MARGIN

SEK thousands	2018	2017
<i>Operating income</i>		
Net sales	187 868	148 342
<i>Operating expenses</i>		
Cost of goods sold	-51 915	-34 946
<b>Gross income</b>	<b>135 953</b>	<b>113 396</b>
<b>Gross margin %</b>	<b>72</b>	<b>76</b>

### Gross margin, non-durable goods

<i>Operating income</i>		
Net sales of non-durable goods	172 693	140 994
<i>Operating expenses</i>		
Cost of non-durable goods sold	-39 406	-30 362
<b>Gross income, non-durable goods</b>	<b>133 288</b>	<b>110 632</b>
<b>Gross margin, non-durable goods %</b>	<b>77</b>	<b>78</b>

### EQUITY/ASSETS RATIO

SEK thousands	181231	171231
Shareholders' equity	540 477	504 332
Total assets	586 612	538 540
<b>Equity/assets ratio %</b>	<b>92</b>	<b>94</b>

## CERTIFICATION

The Board of Directors and the CEO hereby certify that the annual accounts have been prepared in accordance with generally accepted accounting principles in Sweden and have been drawn up in accordance with the international accounting standards referred to in Regulation (EC) No 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of international accounting standards. The annual accounts and the consolidated accounts provide a fair representation of the Parent Company's and the Group's position and performance. The Administration Report for the Parent Company and the Group provides a true and fair overview of the development of the company's operations, financial position and earnings, and describes the significant risks and uncertainty factors to which the Parent Company and the companies included in the Group are exposed.

As indicated above, the annual accounts and the consolidated annual accounts were approved for release by the Board of Directors and the CEO on April 2, 2019. The consolidated statement of net income and the consolidated statement of total comprehensive income as well as the consolidated statement of financial position and the income statement and balance sheet for the Parent Company are subject to adoption at the Annual General Meeting to be held on April 25, 2019.

April 2, 2019  
Gothenburg

Gösta Johannesson  
Chairman of the Board

Magnus Nilsson  
CEO

Folke Nilsson  
Member of the Board

Erik von Schenck  
Member of the Board

Camilla Öberg  
Member of the Board

Alan Raffensperger  
Member of the Board

Yvonne Mårtensson  
Member of the Board

Our auditor's report was submitted on April 2, 2019

KPMG AB

Jan Malm  
Authorized Public Accountant

# AUDITOR'S REPORT

To the general meeting of the shareholders of XVIVO Perfusion AB (publ),  
corp. id 556561-0424

## REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

### OPINIONS

We have audited the annual accounts and consolidated accounts of XVIVO Perfusion AB (publ) for the year 2018, except for the corporate governance statement on pages 31-34. The annual accounts and consolidated accounts of the company are included on pages 27-52 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of the parent company as of 31 December 2018 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2018 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 31-34. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

### BASIS FOR OPINIONS

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### KEY AUDIT MATTERS

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

#### REVENUE RECOGNITION

See disclosure 2 and accounting principles on page 42-43 in the annual account and consolidated accounts for detailed information and description of the matter.

##### *Description of key audit matter*

Revenue for 2018 in the Group amounted to 187.9 MSEK. Revenue for sale of goods is reported in the income statement when significant risks and benefits associated with the ownership of the goods have been transferred to the buyer, which normally occurs in connection with the loan loss. Normally revenue is reported when the buyer accepts delivery, and installation and control have been made. Revenue can also be reported as soon as delivery has taken place but not installation, if it is stipulated in the agreement that risks and benefits with delivery have passed to the buyer.

Sales refers to revenue from sales of goods and services and invoiced freight and is reported excluding VAT, returns and discounts. Billing takes place in connection with delivery. Revenue is reported at the fair value of what has been received or will be received for goods and services sold in the Group's ongoing operations.

##### *Response in the audit*

We have assessed the design of the company's controls regarding revenue reporting of goods and services and how these controls have been implemented.

We have reviewed a selection of contracts to analyze the relevant contractual relationships and how these have been reported, as well as the assessment of the profitability of the applied income statement. We have examined, on a selection basis, sales transactions reported before and after the year-end to assess whether correct terms have been applied to the contract and that risks and benefits have been transferred to customers.

We have checked by sampling that reported revenues are consistent with information in the delivery system. We have also verified the security of IT systems and that there are controls between the systems and accounts so that revenue is recognized in the accounting period when delivery has taken place.

#### VALUATION OF GOODWILL AND CAPITALIZED EXPENDITURE FOR DEVELOPMENT

See disclosure 14 and accounting principles on page 43 in the annual account and consolidated accounts for detailed information and description of the matter.

##### *Description of key audit matter*

As of 31 December 2018, the Group reported goodwill of SEK 65.6 million and capitalized development costs of SEK 214.1 million, representing 48% of total assets. Goodwill will be subject to at least one so-called impairment test, which contains both complexity and significant elements of assessments from the management of the Group. An impairment test must be prepared for each of the cash-generating units, which for the Group is a unit.

Goodwill refers in its entirety to the business of perfadex sales.

Balanced expenses for development work primarily relate to the activities of cardiac transplantation and sales of XPS and STEEN Solution in the US market. In the Parent Company, shares in subsidiaries are reported for an amount of 161.2 MSEK, the value is largely affected by the assessment of goodwill and capitalized expenses for development work carried out in the Group.

The test should be carried out according to the applicable regulations according to a certain technique where management must make future assessments of the company's internal and external conditions and plans. Examples of such assessments are future payments and deposits, which imply assumptions about future market outlets indirectly about how competitors can be expected to act. Another important assumption is which discount rate should be used to take into account that future assessed payments are associated with risk and are therefore less than liquid funds that are directly available to the Group.

##### *Response in the audit*

We have inspected the company's impairment tests to assess whether they are implemented in accordance with the technology provided. In addition, we have assessed the fairness of future payments and the assumed discount rate by taking part in and evaluating management's written documentation and plans. We have also interviewed management and evaluated previous years' assessments in relation to actual outcomes.

We have involved our own valuation specialists in the audit team in order to ensure experience and expertise in the field, primarily regarding assumptions related to external markets and competitors as well as assessment of the company's assumptions regarding future payments.

An important part of our work has also been to evaluate how changes in assumptions can affect the valuation, that is, performing and taking part in the Group's so-called sensitivity analysis.

We have also checked the completeness of the disclosures in the annual report and assessed whether they are consistent with the assumptions applied by the Group in its impairment test and if the information is sufficiently comprehensive to understand management's assessments.

## OTHER INFORMATION THAN THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 27-52. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

## RESPONSIBILITIES OF THE BOARD OF DIRECTORS AND THE MANAGING DIRECTOR

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

## AUDITORS RESPONSIBILITY

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error; and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's, use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report

to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

## REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

### OPINIONS

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of XVIVO Perfusion AB (publ) for the year 2018 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

### BASIS FOR OPINIONS

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

## RESPONSIBILITIES OF THE BOARD OF DIRECTORS AND THE MANAGING DIRECTOR

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner.

The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

## AUDITOR'S RESPONSIBILITY

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

## THE AUDITOR'S EXAMINATION OF THE CORPORATE GOVERNANCE STATEMENT

The Board of Directors is responsible for that the corporate governance statement on pages 27-30 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR's auditing standard RevU 16. The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

KPMG AB, Box 11908, 404 39 Göteborg, was appointed auditor of XVIVO Perfusion AB (publ) by the general meeting of the shareholders on the 26 April 2017. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2013.

Göteborg 2 April 2019

KPMG AB

Jan Malm  
Authorized Public Accountant

# BOARD OF DIRECTORS



**Gösta Johannesson**  
*Chairman of the Board*

Born 1959. B.Sc. in Business Administration and Economics at Uppsala University. Senior advisor at Bure Equity AB.

Other Board assignments: Chairman of the Board in Idevall & Partners Fonder AB, Yubico AB and Atle Investment Services AB. Board member in Interflora AB and Deputy Chairman of the Board in Axiell Group. Previous assignments: Partner at Provider Venture Partners, executive positions at Öhman Fondkommission and Handelsbanken Markets.

Shareholding in XVIVO Perfusion: 2000 shares.



**Erik von Schenck**

Born 1964. M. Sc. ME and Executive MBA. Vice President Global R&D at Stryker Emergency Care.

Other Board assignments: Chairman of the Board in Avidicare AB and BiBB AB. Board member in Life Science Washington and in a number of small med tech companies. Previous assignments: CEO for Jolife AB and Jostra AB. Management positions in Gambro AB.

Shareholding in XVIVO Perfusion: 0 shares.



**Folke Nilsson**

Born 1950. MD, PhD. at University of Gothenburg. Specialist in Cardiothoracic surgery and currently general practitioner.

Other Board assignments: none. Previous assignments: Responsible for heart and lung transplantation at Sahlgrenska Universitetssjukhuset.

Shareholding in XVIVO Perfusion: 0 shares.



**Yvonne Mårtensson**

Born 1953. M.Sc. Ind. Eng. at Linköpings University.

Other Board assignments: Chairman of the board in Elos Medtech AB, board member in Biotage AB, SyntheticMR AB and 3Brain AG. More than thirty years' experience from leading positions in fast growing companies primarily within medtech and diagnostic. Earlier CEO for CellaVision AB during 1998-2014.

Shareholding in XVIVO Perfusion: 3 000 shares.



**Alan Raffensperger**

Born 1960. MBA from George Washington University and a B.Sc. in Health Services Management from University of Maryland Baltimore. CEO Inceptua SA.

No other Board assignments. More than thirty years' experience from leading positions in fast growing companies primarily within biotech, medical device and diagnostics. Previously COO for SOBI (Swedish Orphan Biovitrum AB) during 2012-2017 and before that, during 2010-2012, CEO for Benechill Inc.

Shareholding in XVIVO Perfusion: 0 shares



**Camilla Öberg**

Born 1964. B.Sc. in Business Administration from Stockholm School of Economics. CFO at Cybercom Group.

Other Board assignments: Boardmember at Instalco Intressenter AB. Previous assignments: CFO at Logica Sverige, management positions at WM-data, Swegro Group, Lexicon and SEB (e.g. Investor Relations, Treasury and Business Control).

Shareholding in XVIVO Perfusion: 1 000 shares

## AUDITORS

The company's auditor is KPMG AB. Principal auditor is Authorized Public Accountant Jan Malm (born 1960).

KPMG AB Street Address: Norra Hamngatan 22  
404 39 Göteborg  
Phone +46 31 61 48 00

*Shareholdings include the holdings of spouses, minor children and related companies.*

# SENIOR MANAGEMENT



Christoffer Rosenblad  
CFO, deputy CEO

Katrin Gisselfält  
Quality and Regulatory Director

Magnus Nilsson  
CEO

Henrik Isaksson  
Operations Director

Emur Jensen  
Development Director

Pär-Ola Larsson  
Marketing and Sales Director Europe,  
Middle-East, Africa and Pacific

## **Magnus Nilsson** **CEO**

Born 1956, Doctor Med. Sc. at Uppsala Universitet. CEO in XVIVO Perfusion from 2011 and before that CEO in Vitrolife since 2003. Before that project leader for preclinical and clinical development, KaroBio AB and Pharmacia & Upjohn AB.

Shareholding in XVIVO Perfusion: 200 000 shares and 72 000 warrants.

## **Pär-Ola Larsson** **Marketing and Sales Director Europe,** **Middle-East, Africa and Pacific**

Born 1969. B. Sc. Business Administration at University of Gothenburg and Executive MBA from Copenhagen Business School. Previous assignments: Business Development Manager Pulmonary and Bronchial Thermoplasty at Boston Scientific. Managerial positions within sales, marketing and business development at Johnson & Johnson.

Shareholding in XVIVO Perfusion: 2 500 aktier and 36 000 warrants.

## **Christoffer Rosenblad** **CFO, deputy CEO**

Born 1975. M. Sc. Mech. Eng. and B. Sc. Fin Ec. Previous assignments: Business Controller at Ciba Vision Nordic AB and financial positions at LG Electronics.

Shareholding in XVIVO Perfusion: 54 392 shares and 36 000 warrants.

## **Katrin Gisselfält** **Quality and Regulatory Director**

Born 1969, Ph.D., Polymer Chemistry, Chalmers University of Technology. Previously R&D and Regulatory Affairs Director at Abigo Medical AB and before that VP R&D with responsibility for R&D, Regulatory and clinical studies at Artimplant AB.

Shareholding in XVIVO Perfusion: 0 shares.

## **Henrik Isaksson** **Operations Director**

Born 1971, B. Sc. Business and Economics with additional graduate studies in Business. Previously Senior Manager Sourcing and Supply Chain at Stryker and before that Product Manager and Supply Manager positions at Ericsson and Gambro.

Shareholding in XVIVO Perfusion: 0 shares and 18 000 warrants.

## **Emur Jensen** **Development Director**

Born 1972. B. Sc. Chem. Eng. and Professional engineer license for the state of Colorado. Previous assignments: Plant Manager for Vitrolife Inc. Engineering and process development for C&MI Inc.

Shareholding in XVIVO: 2,000 shares.

*Shareholdings include the holdings of spouses, minor children and related companies.*

# 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).

# DEFINITIONS

KPI	DEFINITION	MOTIVATION
Gross margin excluding capital goods, %	Gross profit for the period segment all non-capital goods divided by the period's net sales segment all non-capital goods.	The company believes that the key figure provides an in-depth understanding of the Company's profitability regarding its operations without capital goods. Since the pricing strategy for capital goods differs from the pricing strategy from all other operations, the gross margin is reported separately without capital goods.
Gross margin, %	Gross profit of the period divided by net sales of the period.	The company believes that the key figure provides an in-depth understanding of the Company's profitability.
EBITDA margin, %	EBITDA (Operating profit before depreciation for the period) divided by the period's net sales.	The company believes that the key figure provides an in-depth understanding of the Company's profitability.
Operating margin, %	Operating profit for the period divided by the period's net sales.	The company believes that the key figure provides an in-depth understanding of the Company's profitability.
Net margin, %	Profit of the period divided by net sales of the period.	The company believes that the key figure provides an in-depth understanding of the Company's profitability.
Solidity, %	Shareholders' equity divided by balance sheet total.	Equity ratio shows the size of the Equity in relation to the balance sheet total and has been included in order for investors to be able to create an image of the Company's capital structure.
Equity per share, SEK	Shareholders' equity divided by the number of shares outstanding on the balance sheet date.	The key figure has been included so that investors should get an overview of how the Company's equity per share has developed.
Earnings per share, SEK	Profit for the period divided by the average number of shares, before dilution, for the period.	The key figure has been included so that investors will get an overview of the respective period's dividends.
Earnings per share after dilution, SEK	Profit for the period divided by the average number of shares, after dilution, for the period.	The key figure has been included so that investors should get an overview of how the Company's share price has developed.

## XVIVO PERFUSION'S PRODUCTS

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



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

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