



# **ANNUAL REPORT 2020**

## XVIVO PERFUSION AB (PUBL)

## CONTENT

XVIVO Perfusion in brief	2
Key events in 2020	3
CEO has the floor	4
Business concept, goals and strategies	7
Business model	12
Sustainability	15
Transplantation	20
Organ donation - the gift of life	25
XVIVO Perfusion's offer	26
Trends and market	34
Research and Development	38
The Share	40
 FINANCIAL REPORT	
Administration Report	42
Corporate Governance Report	48
Financial statements - Group	52
Financial statements - Parent Company	55
Additional information and notes	58
Auditor's report	69
 Board of Directors, auditors and senior management	72
Glossary and definitions	74

## XVIVO PERFUSION IN BRIEF



More and more people in the world are in favor of donating their organs, but despite this, there is still a great shortage of available organs. According to the WHO, more than 160,000 organ transplants are performed annually worldwide, but this represents only 10 percent of the total need. The lack of organs means that many patients die while waiting for an organ, or become so deconditioned from their illness that they would not survive the transplant procedure and are therefore removed from the waiting list. In the United States alone, 20 people a day die waiting for a new organ.

XVIVO Perfusion is a medical device company that develops and markets innovative solutions and systems for preserving and evaluating donated organs outside the body while waiting for transplantation.

The company is active in all four major organ areas (kidney, liver, heart and lung) and consists of two business areas: Thoracic (heart and lung) and Abdominal (liver and kidney). In lung transplantation, the company's product Perfadex Plus has a market share of approximately 90 percent in the traditional static preservation of lungs for transplantation. The company's products for warm perfusion, XPS and STEEN Solution, have gained regulatory approval in all major markets, and were the first products that received regulatory approval from the FDA for warm perfusion of marginal lungs. In liver and kidney transplantation, XVIVO Perfusion develops and sells machine perfusion products, which clinical studies have shown to increase organ survival rates. XVIVO Perfusion also develops the next generation pre-transplant heart preservation products that optimize storage and transport of donor hearts through non-ischemic heart perfusion.

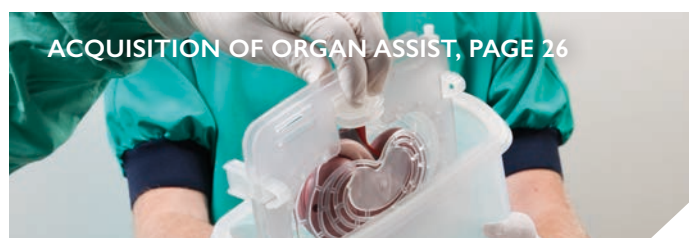
XVIVO Perfusion employs around 80 people. The head office is located in Gothenburg and its subsidiaries are located in Lund, Sweden, Denver, USA and Groningen, Netherlands. XVIVO Perfusion's share is listed on NASDAQ Stockholm and trades under the XVIVO ticker.

We are dedicated to our vision that "Nobody should die waiting for a new organ" and are proud that our groundbreaking innovations have helped more patients to undergo transplantation and thereby have the chance of a longer and better life. Alongside leading researchers and transplantation clinics, we help to develop solutions that make a difference – for the patient, the transplant team and for society.

PERFADDEX® and PrimeECC® are registered trademarks of XVIVO Perfusion. STEEN Solution™, XPS™, XVIVO LS™, XVIVO Disposable Lung Set™, XVIVO Organ Chamber™, XVIVO Lung Cannula Set™, XVIVO Silicone Tubing Set™ are trademarks of XVIVO Perfusion.

# SIGNIFICANT EVENTS IN 2020

- First patient enrolled in the European Heart preservation study.
- A study published in the Lancet showed better survival of transplanted kidneys after cold machine perfusion with added oxygen.
- XVIVO Perfusion acquired Dutch med tech company Organ Assist.
- Directed share issue raised SEK 500 million.
- First patient in the extended PrimECC study enrolled.
- Strategic plan 2025 adopted and new organization launched
- Magnus Nilsson passed the baton as CEO to Dag Andersson.
- Heart preservation study from Skåne University Hospital published in Nature Communications demonstrating safety of the technology.
- International launch of enhanced and more user-friendly version of Perfadex Plus with Click Port.



## SALES

**SEK 180 million**

## SHARE, MACHINE PERFUSION\*\*

**43%**

## ADJUSTED EBITDA MARGIN\*\*

**11%**

## SALES, SEK MILLION



## GROUP KEY RATIOS

	2020	2019
Gross margin excluding durable goods, %	77	77
Gross margin, %	74	74
EBITDA, %**	-9	13
Adjusted EBITDA, %**	11	16
Operating margin, %	-25	2
Net margin, %	-24	2
Equity ratio, %	88	91
Earnings per share, SEK	-1.61	0.19
Equity per share, SEK	35.11	21.71
Share price as of the balance sheet date, SEK	314	170

Machine perfusion is a new technology that improves preservation and evaluation of organs, which means more organs can be used for transplants. In the Thoracic business area, this includes STEEN Solution, XPS, XVIVO LS and Lung Assist, as well as other products and services related to the use of these machines. In the Abdominal business area, this includes Kidney Assist Transport, Kidney Assist, Liver Assist and Donor Assist, as well as other products and services related to the use of these machines. The share of machine perfusion corresponds to sales of products and services for machine perfusion as a proportion of total sales of products and services. | \*\* Adjusted EBITDA represents EBITDA for the period adjusted for costs of warrants programs for employees outside Sweden, integration costs attributable to acquisitions and reorganization costs.



# FIRST IN THE WORLD TO OFFER PRODUCTS IN ALL FOUR MAJOR ORGAN AREAS

For XVIVO Perfusion, 2020 was a successful year in several respects. We appointed a new management during the year and determined the strategy for the period until 2025. There is now a clear and distinct plan for how XVIVO Perfusion will continue to grow profitably in the coming years and become an even stronger contender in the transplant area.

In September 2020, we acquired an exciting Dutch company, Organ Assist, active primarily in machine preservation of liver and kidney. The acquisition means that we are now able to address all four major organ areas. Of all organs that are transplanted annually, lung and heart account for 10 percent and kidney and liver for 88 percent.

The strong confidence in XVIVO and the company's strategy was demonstrated by last fall's successful capital raising, which strengthened and broadened the company's ownership base.

In 2020, we strengthened the organization in several areas. We added new sales resources in North America, Europe and China. We also strengthened our research and development organization to ensure our ability to deliver prioritized projects.

### **Sales recovered**

Our sales were negatively affected by the COVID-19 pandemic from the second quarter onwards. However, the market started to recover at the beginning of the third quarter, which contributed to total net sales for the full year of SEK 180 million (221).

EBITDA for the period, adjusted for costs relating to the issue of warrants for employees outside Sweden and integration costs attributable to acquisitions, amounted to SEK 20 million (36). This corresponds to an EBITDA margin of 11 percent (16), which I am satisfied with considering the challenges the pandemic has caused.

It is my belief that we will have to live with the reality that the pandemic brings for a large part of 2021. We have an ambitious commercial plan for the full year, but should expect that 2021 will start weaker than a normal year, then gradually improve in conjunction with the recovery of the global transplant industry.

### **R&D in focus**

In 2021, we intend to increase investments in research and development more than we have done in any previous year. We have several prioritized projects underway. In 2020, our clinical studies were affected by the Covid-19 pandemic as many hospitals in many countries temporarily halted their research programs. The clinical studies linked to our heart project started in earnest in the fourth quarter with recruitment of patients in both Belgium and Sweden.

Another very interesting advance in research was highlighted in an article published in the prestigious scientific journal, The Lancet last fall. The article shows that oxygenated perfusion of kidneys using XVIVO's products during transport to the hospital

has a significant positive impact on first-year results after transplantation. Researchers found that in the group with oxygenated perfusion, significantly fewer patients experienced a complete loss of kidney function after the transplant, only 3 percent compared to 10 percent in the group that did not receive this treatment. One of our goals for 2021 is to commercialize the upgraded kidney transport unit that enabled the positive results achieved in the study.

### **New company – new brand**

In 2021, there will also be important changes to our brand platform and our brand guidelines. As a consequence of the acquisition of Organ Assist, we need a platform and visual identity that clearly shows that the new XVIVO Perfusion has machines and solutions for all major organ areas.

### **Priorities in 2021**

A very exciting period lies ahead. The integration of Organ Assist is one of our priorities for 2021. We will primarily focus on ensuring that the sales organization can handle our more complete range of machines and solutions for all major organ areas.

Our heart preservation project will remain the focus of our research and development work. In addition to the studies started in Europe, we plan to initiate studies in Australia in the beginning of the year and to initiate our study in the USA before year end.

We will also seek regulatory approval for the new oxygenated kidney transport unit in Europe and North America. We are convinced that there is great potential in this product. Another product with a great potential is our liver perfusion machine, for which we aim to submit an application to FDA during 2021 to obtain regulatory approval on the American market.

Finally, we will continue to clarify the positive results, effects and values generated by our products. With a product portfolio that is best in class we can actively work on our price strategy and ensure continued great margins on our products.

It has been a rewarding first year for me in my role as CEO. I am very impressed by my colleagues' high level of competences and strong commitment. I would like to thank my colleagues at XVIVO Perfusion for their efforts and resilience during the year, and welcome you to join me in developing the company during 2021 and in future.

Dag Andersson, CEO





OUR VISION IS  
THAT "NO ONE  
SHOULD HAVE TO  
DIE WAITING FOR A  
**NEW ORGAN**"

# BUSINESS CONCEPT, GOALS AND STRATEGIES

XVIVO Perfusion's vision is that no one should have to die waiting for a new organ. For more than 20 years, the company has developed innovative products to make more organs available for transplantation. We are the market leaders in lung transplants and the leaders in research in organ perfusion. During the year, we adopted a new strategy for 2021–2025 focused on becoming world-leading in all major organs and strengthening our commercial potential.

## Vision

XVIVO Perfusion's vision is that "no one should have to die waiting for a new organ".

## Business concept

The business concept is to develop and market effective products for preserving and evaluating organs outside the body while awaiting transplant.

This means that XVIVO Perfusion can increase availability of organs with good survival potential during transplantation.

## Strategy and targets to 2020

Between 2018 and 2020, XVIVO Perfusion's strategy focused on increasing the number of available organs for transplantation by:

- Maintaining its position as market leader in cold preservation of lungs
- Establishing warm perfusion as a standard treatment in lung transplantation
- Expanding operations to other organs

In 2020, XVIVO Perfusion worked towards the following specific targets:

- Continued establishment of the use of XPS and STEEN Solution worldwide
- Begin multicenter clinical studies for heart transplantation
- Expand the clinical documentation of PrimECC with multicenter clinical studies

## Operational targets

The operational targets from 2021 are:

- Obtain FDA approval in the US for Kidney Assist Transport machine
- Establish organization for the Abdominal area in the US.

The operational targets to 2025 are:

- Offer a complete product portfolio for lung, heart, liver and kidney transplantation by 2025
- Become the world leader in preservation and evaluation of donated organs.

## OUR JOURNEY TO DATE

**1998** XVIVO Perfusion is founded by Magnus Nilsson when he acquired the rights to PERFADEX.

XVIVO Perfusion initiates collaboration with Professor Stig STEEN at Lund University. The aim is to develop new technology for warm perfusion of lungs.

**2006** STEEN Solution for warm perfusion of lungs is approved for sales in Europe.

**2008-2014** Intensive development work resulted in the XPS, a machine for warm perfusion of lungs. Plus FDA HDE approval.

**2012** XVIVO Perfusion is distributed to the shareholders of Vitrolife and listed on the NASDAQ OMX First North.

**2016** XVIVO Perfusion acquires Vivoline Medical AB and expanded the product portfolio within lungs as well as took over control of an advanced development project for the storage and evaluation of heart.

**2017** The first clinical heart transplant using the new heart preservation technology for donated hearts developed by XVIVO Perfusion carried out.

**2019** XVIVO Perfusion received PMA (Pre Market Approval) approval from the US FDA for the products XPS and STEEN Solution system.

**2020** XVIVO Perfusion acquires the Dutch medical technology company Organ Assist and becomes first in the world to actively conduct business in all four major organ areas.

STRATEGIC GOALS 2020	DEVELOPMENTS IN 2020
<b>Maintaining its position as market leader in cold preservation of lungs</b> PERFADEX has been the market standard for lung preservation for over 15 years. The solution is used in more than 90 percent of all lung transplants performed worldwide.	The enhanced and more user-friendly Perfadex Plus with Click Port was launched worldwide. This was a key milestone as this version is easier to use, which reduces the risk of error handling and increases patient safety.
<b>Establish machine perfusion as the standard treatment for lung transplantation</b> Only 20-30 percent of all donated lungs go to transplantation. Meanwhile, approximately 20 percent of patients on the waiting list die while waiting for new lungs. The EVLP method with STEEN Solution provides more available organs. This results in life-saving treatments for more patients, improved quality of life and socio-economic benefits.	Total sales from machine perfusion for the year represented 37 percent (47) of total sales. The decrease was due to fewer EVLPs carried out as healthcare operators on many markets have been forced to prioritize emergency care as a result of the Covid-19 pandemic.  University Hospital AKH in Vienna, one of the largest clinics for lung transplants in Europe, was one of the clinics that purchased an XPS.
<b>Expand to other organs</b> XVIVO focuses on enabling more transplantations of organs other than lungs. To begin with, the goal was to expand to heart transplants, and later also to liver and kidney. The initiative is based on XVIVO Perfusion's strong position in lung transplantation, and its established network in thoracic surgery.	During the year, XVIVO Perfusion acquired the Dutch medical technology company Organ Assist B.V. Organ Assist develops machines and consumables for perfusion of liver and kidney. The acquisition made XVIVO Perfusion the first company in the world, within preservation and evaluation of transplantable organs, to actively conduct business in all four major organ areas, and the company achieved its strategic goal of expanding to liver and kidney.  The scientific journal Nature Communications published an article about XVIVO Perfusion's use of heart preservation technology. The single-center study describes the heart preservation method as safe.  The first patient in XVIVO's European Heart preservation study received a transplant at the end of the year. The patented technology developed by Professor Stig Steen and commercialized by XVIVO Perfusion, uses a novel technique for preservation of the donor heart during transport. The study forms the basis of a European regulatory approval application and will investigate if the new technology can improve patient outcomes and reduce complications after heart transplantation.  An article published in the scientific journal The Lancet shows that oxygenated perfusion of kidneys before transplantation has a significant positive impact on how the body reacts to the transplanted organ in the first year after transplantation. The Kidney Assist Transport device, used in the trial, has been developed by Organ Assist and is CE-marked. XVIVO Perfusion plans to apply for FDA approval for the machine in 2021 in order to launch the product in the US.

GOALS 2020	ACTUAL
<b>Continued establishment of the use of XPS and STEEN Solution worldwide.</b>	Progress in the year was limited as a result of the Covid-19 pandemic.
<b>Begin multicenter clinical studies for heart transplantation</b>	One of three studies started as planned in the year; the others are expected to start in 2021. This is also a result of the outbreak of the pandemic.
<b>Expand clinical documentation of PrimECC with multicenter clinical studies.</b>	First patient included in XVIVO Perfusion's extended PrimECC study. PrimECC is a fluid used to prime heart-lung machines for surgery. The fluid aims to reduce complications after heart surgery. The extended study that has now begun intends to expand the clinical documentation for PrimECC and will include a total of 366 patients.



# OUR STRENGTHS

## THE WORLD LEADER IN LUNG TRANSPLANTATION

XVIVO Perfusion is a strong brand in lung transplantation and is the market leader in both cold preservation and warm perfusion of donated lungs.

## ESTABLISHED NETWORK IN ORGAN TRANSPLANTATION

XVIVO Perfusion has a global market presence and long established relationships with world-leading researchers and transplant clinics around the world.

## EXPERTS IN ADVANCED SOLUTIONS FOR TRANSPLANTATION

Together with Igelösa Life Science and Professor Stig STEEN, XVIVO Perfusion has developed unique solutions for caring for organs outside the body for more than 20 years.

## PROFITABLE GROWTH

XVIVO Perfusion returned growth and positive EBITDA every quarter since the share was listed in October 2012, a trend that was interrupted in 2020 as a result of the Covid-19 pandemic.

## SUCCESSFUL ORGANIZATION FOR INNOVATION

XVIVO Perfusion has extensive experience in research and development, through the process of obtaining regulatory approval and the various phases of market launch.



# NEW STRATEGY 2021–2025

XVIVO Perfusion's strategy for the period 2021 to 2025 focuses on commercial operations and optimizing availability of relevant products for organ donation when and where they are needed. The goal is that no one should have to die while waiting for a new organ.

In the period since the company was founded more than 20 years ago, we have built solid competences and capacity in research, development and the regulatory field. We are now developing further with a new management and organization, and are focusing on five strategic areas: an offer that includes all four major organs, bringing innovation closer to our customers, building a high-performing organization, strengthening our commercial ability and developing the company's operations.

## STRATEGIC AREAS

### THE WORLD LEADER IN ALL MAJOR ORGANS

XVIVO Perfusion will build on its strong position in lung transplantation and develop the offer to include machines, solutions and other products for preservation and evaluation of all four major organs; lungs, heart, kidney and liver. The transition from what was essentially one product group for a single organ to a product portfolio that includes multiple organs is equally important and challenging. XVIVO Perfusion's progress in kidney and liver is largely due to the acquisition of Organ Assist.

### CUSTOMER-DRIVEN INNOVATION

To develop XVIVO Perfusion commercially, we will bring innovation and progress even closer to our customers. This allows us to benefit from our good relationships with institutions and clinics, and our strong position in research and development. By increasingly proceeding from customer insights, we reduce the time needed for commercialization of new products and strengthen our customers' perception of and loyalty towards XVIVO Perfusion and our products.





## HIGH-PERFORMING ORGANIZATION

XVIVO Perfusion has developed its leading research and development competences and capacity over many years. The next phase consists of building an even more efficient organization to ensure the successful commercialization of XVIVO Perfusion's products in the shortest possible time.

The first steps were taken in the year and included a reorganization and the appointment of several key positions.

## COMMERCIAL POTENTIAL

To expand in the manner we want, XVIVO Perfusion will become commercially stronger. This includes developing our competences and capacity in marketing and sales. We are also preparing the company for geographical expansion in Asia (particularly China), the Middle East (particularly Saudi Arabia) and Latin America (particularly Brazil). Finally, we will clarify the positive results, effects and values generated by our products. The aim is also that pricing will mainly be based on results and value.

## OPERATIONAL STRENGTH

XVIVO Perfusion's commercial potential is closely associated with our operational strength. A clearer operational focus will imply careful review and selection of projects, designs that are adapted to manufacture, fewer distribution points and improved cost efficiency and delivery reliability. The aim is a relevant and profitable product portfolio that generates the greatest possible benefit for customers and patients.



# BUSINESS MODEL – FROM RESEARCH TO SALES

XVIVO Perfusion's business model aims to strengthen our leading position in organ transplantation by successfully taking groundbreaking innovations from idea to marketable product. The business model includes long-term relationships in innovation and research as well as close collaborations with selected partners.



## INNOVATION AND RESEARCH

XVIVO Perfusion's research is mainly carried out in collaboration with world-leading institutions and researchers. By conducting different research projects alongside with partners in the US, Canada and EMEA, we ensure our level of competence in the clinical field and that we remain at the forefront of clinical development.



## PRODUCT DEVELOPMENT

Product development largely takes place in-house at our head office in Gothenburg (for solutions), at the subsidiaries in Lund (for heart), in Denver (for lung) and Groningen (for kidney and liver). Good knowledge of manufacturing methods and regulatory requirements allows us to streamline the process and shorten the time to market.



## CLINICAL STUDIES & REGISTRATION

Clinical studies are of great importance to XVIVO Perfusion, partly because they form the basis for approval of products, but also for expanding the fields of application. Pre-clinical and clinical studies are conducted in collaboration with hospitals and universities. In order to introduce the products to each market, regulatory approval is required. The regulatory landscape has become increasingly complex as the demands of the authorities have increased. XVIVO Perfusion's regulatory work ensures that our innovations reach all markets in the shortest possible time.

### Patent protection for intellectual property rights

XVIVO Perfusion invests heavily in research and development. Patent protection is important to XVIVO Perfusion's business areas, as product cycles are long and investments in product development are significant. XVIVO Perfusion continuously files applications for patents to protect existing and future products. Currently XVIVO Perfusion has 15 families of patents or patent applications at different stages.

XVIVO has two main patents in the field of heart transplantation. One covers the solution used in heart preservation; this patent is valid until 2035. The second includes important parts of the equipment used for heart evaluation after preservation, but before transplantation. The patent is valid until 2036. Together, these patents strengthen XVIVO's position in heart transplantation on all major global markets. In addition to the two main patents, XVIVO Perfusion also holds patents for products and product families:

**STEEN Solution:** STEEN Solution, our liquid for warm perfusion of lungs, is protected by patents in 15 countries, including EP validations. The patents are valid until 2021/2022 and protect both the product and the use of STEEN Solution.

**PrimECC:** PrimECC, XVIVO Perfusion's solution for use in heart-lung machines, is currently protected by patents in 15 countries, including EP validations. The patents are valid until 2031. The U.S. patent protects the use of a solution similar to PrimECC for use in priming heart-lung machines.

**PERFADEX Plus:** PERFADEX Plus is protected by a patent approved in Europe to date.

XVIVO Perfusion owns all rights to the products it markets.

### MANUFACTURE



The production of XVIVO Perfusion's products mainly takes place through carefully selected subcontractors. By outsourcing the manufacturing process, we avoid costly investments in production equipment and can focus on our core business. At the same time, it provides greater flexibility in the event of increased/reduced demand. Long-term and close cooperation with our subcontractors is of great importance in order to meet XVIVO Perfusion's high quality standards.

### MARKETING & SALES



XVIVO Perfusion's products are marketed by its commercial organization in Europe and North America and is mainly distributed directly from Gothenburg, Denver and Groningen. On other markets the company uses distributors. The commercial organization works closely with transplantation centers to support the use of XVIVO Perfusion's products. Our customers' experience and opinions are taken into account in relation to all market innovation, product development and market processing.

### AFTER-MARKET SUPPORT & SERVICE



User training and technical training are an important part of our customer and after-market support. XVIVO Perfusion's in-house organization is responsible for installation, training, service and support. XVIVO Perfusion provides training locally and at the company's training facilities in Denver, Lund and Groningen. In addition, the company offers clinics advanced training and exchange of experience.



A photograph of three men walking in an office hallway. The man on the left is bald, wearing glasses and a dark blue button-down shirt, carrying a laptop. The man in the middle is wearing a black hoodie and holding a laptop. The man on the right is wearing glasses and a light-colored checkered button-down shirt, smiling. The background shows a modern office interior with warm lighting and glass partitions.

“OUR EMPLOYEES’  
**COMMITMENT,**  
**COMPETENCES AND**  
**EFFICIENCY** ARE KEY  
TO OUR **SUCCESS**”



# SUSTAINABILITY

XVIVO Perfusion seeks to contribute to social progress and improve human health. Our responsibility includes both our employees and relationships with external stakeholders. XVIVO Perfusion's operations are global, and a sustainable business strategy that contributes to a healthier and cleaner world is an important key to success.

## INTERNAL CONTROL AND ORGANIZATION

The Board has the overall responsibility for XVIVO Perfusion's organization and internal control under the Companies Act. The Board monitors management's work through monthly reports that include financial results, key figures and results in prioritized activities. The work also includes follow-up of the company's sustainability work. XVIVO Perfusion's sustainability work is led and coordinated by the company's CFO. The company's task force for sustainability includes representatives from key functions such as research and development, purchasing and production, quality control, HR and markets.

### Code of Conduct

The company's Code of Conduct is XVIVO Perfusion's primary sustainability policy. This includes guidelines for business principles, human rights and working principles.

The Code of Conduct is based on the United Nations Universal Declaration of Human Rights, the International Labour Organisation Declaration on Fundamental Principles and Rights in the Workplace, the UN's Global Compact and the OECD Guidelines for Multinational Enterprises. The Code is reviewed and approved annually by the Board. The Code applies to all employees and sets the standard for professionalism and integrity, with the aim of ensuring that all employees act legally and appropriately in relation to the company's stakeholders.

XVIVO Perfusion's Code of Conduct is available at [xvivoperfusion.com](http://xvivoperfusion.com).

## EMPLOYEES

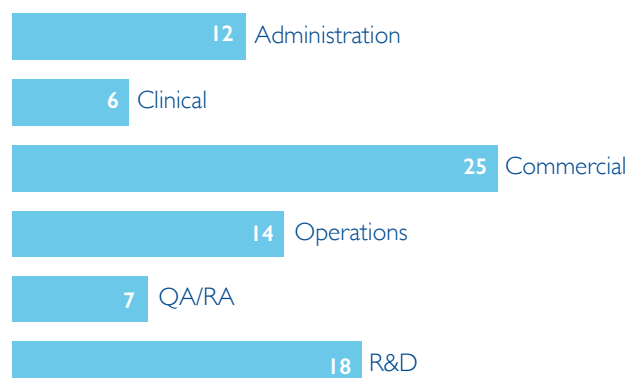
Our employees are proud to contribute to recipients of new organs being able to live longer and better lives.

XVIVO Perfusion employs around 80 people. The head office is located in Gothenburg and our subsidiaries are in Lund, Sweden, Denver, USA and Groningen, Netherlands. XVIVO Perfusion also has employees in several other European countries, and in several US states and Australia. In 2021, we will also establish a sales organization in China.

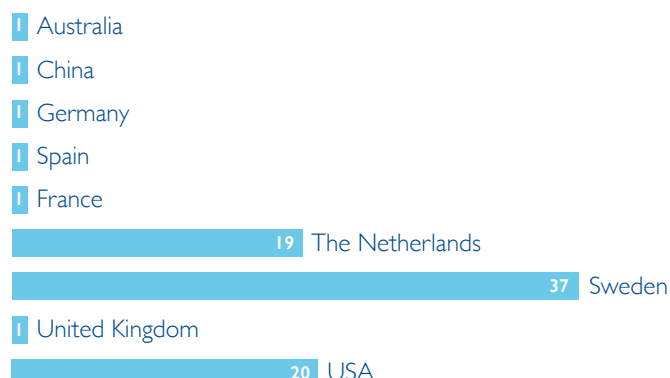
The number of employees increased significantly in the year: 37 new colleagues were employed in XVIVO Perfusion, of which 19 came from Organ Assist, the Dutch company we acquired in 2020. As a result, we have focused sharply on integration, communication and streamlining the organization in the year. Our employees' commitment, competences and efficiency are critical to XVIVO Perfusion's success. We are continuing the expansion and development of the organization.

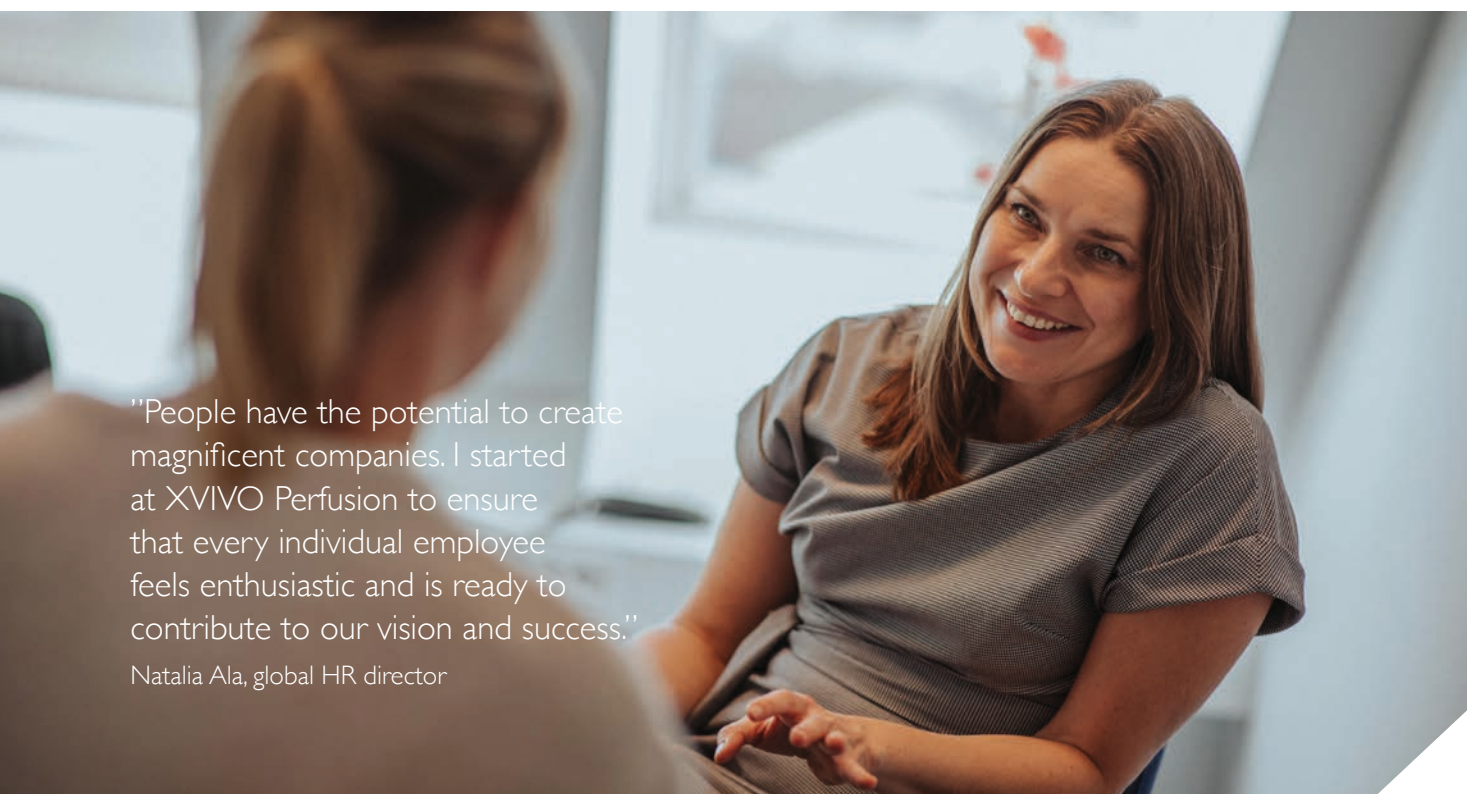
XVIVO Perfusion is a knowledge-intensive company where our employees are the single most important asset for our long-term competitiveness and profitability. XVIVO Perfusion prioritizes and secures our employees' commitment, talent and competence development, market-based remuneration and wellbeing.

## EMPLOYEES PER FUNCTION



## EMPLOYEES PER COUNTRY





"People have the potential to create magnificent companies. I started at XVIVO Perfusion to ensure that every individual employee feels enthusiastic and is ready to contribute to our vision and success."

Natalia Ala, global HR director

### Policies and internal control

XVIVO Perfusion's management of personnel-related matters is based on a number of policies and routines. The most important are our Code of Conduct, the HSEQ policy (including diversity and inclusion), health and safety routines and our integrity policy.

The purpose and aims of the company's HR strategy are largely the same throughout XVIVO Perfusion, although local strategies may vary. XVIVO Perfusion introduced the role of Global HR Manager at the end of 2020. The intention is to drive HR initiatives focusing on commitment, productivity and business value. Another priority is to clarify and streamline HR processes throughout the organization.

XVIVO Perfusion plans to rationalize and strengthen the company's HR processes by implementing a company-wide HR information system. This is part of the strategy aimed at increasing collaboration and efficiency throughout the organization. This will be implemented at the beginning of 2021.

### Employee rights

XVIVO Perfusion respects human rights. Respect for individuals and their integrity and dignity is fundamental to all relations, both within XVIVO Perfusion and in relation to our customers, partners and other external stakeholders. Naturally, XVIVO Perfusion has a special responsibility towards the employees of the company. All XVIVO Perfusion's sustainability-related policies and principles are outlined in the company's Code of Conduct.

XVIVO Perfusion's employees are entitled to join or establish any form of association and to organize themselves and negotiate collectively and individually in accordance with local legislation and regulations. No member of staff shall risk harassment or retribution for exercising these rights.

XVIVO Perfusion is an organization with global operations where language skills and the ability to operate in different cultures are key factors for success. XVIVO Perfusion is a workplace where diversity is respected regardless of gender, gender identity, ethnicity, religion or faith, disability, sexual orientation and age.

### Employment and benefits

In order to attract and retain skilled and competent staff, XVIVO Perfusion increasingly focuses on ensuring efficient working methods and collaboration processes, competitive performance-based remuneration, programs for variable remuneration for key staff and an attractive benefits package.

Remuneration includes insurance benefits. All employees are covered by insurance policies intended to secure employees' and their families' health, wellbeing and safety. Arrangements vary slightly between countries.

### Health and safety

XVIVO Perfusion seeks to ensure a positive working environment and employee health and wellbeing by matching the right person to the right assignment, which provides opportunities for variety and professional development. XVIVO Perfusion also

seeks to meet requests for flexible working hours. The aim is to facilitate a positive work-life balance.

Our employees work in a modern office environment with ergonomic work stations and the opportunity to move around during work. XVIVO Perfusion's main health and safety risks relate to repetitive strain injuries and stress-related illnesses. No accidents in the workplace were reported in 2020. XVIVO Perfusion also provides extensive health benefits, including rehabilitation plans when needed.

### Performance review and personal development

XVIVO Perfusion has a formalized process for following up results in biannual performance reviews. This process involves setting expectations and defining key targets and priorities linked to the company's strategic goals and core values. The reviews also include planning individual development, including leadership, teamwork and working environment. The results of the performance review form the basis for talent development, individual development and salary reviews. The purpose is to develop and retain talented and competent employees.

We take a transparent and constructive approach to the formal performance follow-up as well as in day-to-day work. Mutual exchange and feedback ensure commitment and gives our employees the opportunity to develop as individuals as well as part of a team and the company.

## SOCIAL RESPONSIBILITY

### Corporate culture and core values

Everyone who works at XVIVO Perfusion is dedicated to our vision that "nobody should die waiting for a new organ" and is proud that

our innovations help give patients the opportunity to live longer and better lives. For more than two decades we have focused on developing, manufacturing and marketing technology that contributes to making more donated organs available for transplant.

XVIVO Perfusion has a strong corporate culture with clear values. During the year, we worked on developing our shared values and formulated the core values that guide us in our work. The starting point for this work came from input from our employees, customers and distributors and other collaboration partners. Employees were given the opportunity to make their voices heard in five workshops across all sites, and feedback from other stakeholders was collated in a survey. The work resulted in defining our core values: research-driven, customer-oriented, collaborative and meaningful. The core values will be applied even more in our day-to-day work in future, and in the communication with our employees.

### Research and development

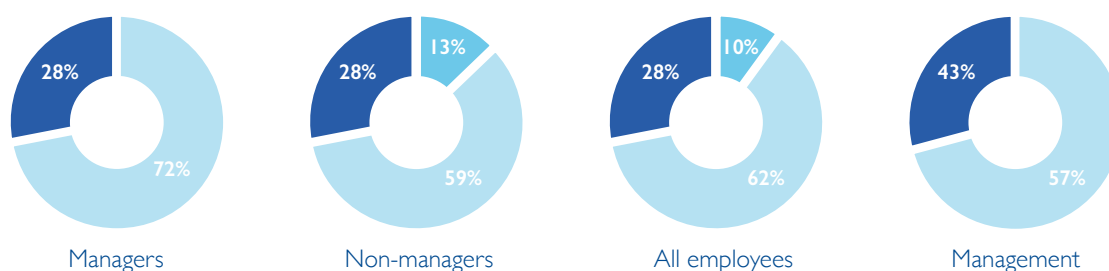
XVIVO Perfusion provides financial support to various research projects carried out by clinics, academic institutions and other external parties. We want to increase the body of knowledge in the field of transplantation, both in order to improve our products and to find new and better solutions for preserving organs outside the body ahead of transplantation.

### Product safety and quality

The high quality and safety of our products is critical to our operations. We assure the quality and safety of our products by complying with applicable legislation and regulations, as well as our internal process-based quality management system. We analyze and review quality continuously throughout the product lifecycle.

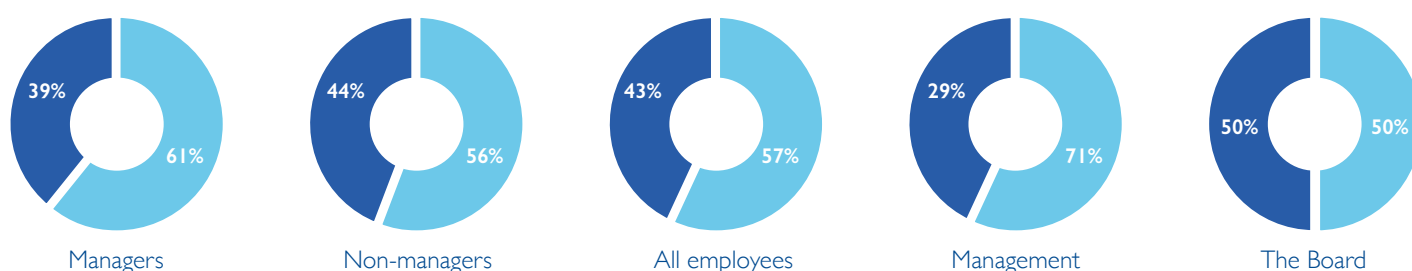
### AGE DISTRIBUTION

■ <30 ■ 30–50 ■ >50



### GENDER DISTRIBUTION

■ Men ■ Women





## "OUR OPERATIONS ARE BASED ON THE PRINCIPLE THAT ALL OPERATIONS ARE FOUNDED ON SOUND BUSINESS ETHICS"

### Quality management system

XVIVO Perfusion has established, documented and implemented a global process-based quality management system. We are dedicated to upholding the efficiency of the system and to continuous improvement. Our unit in Groningen has a local quality control system and staff that are responsible for local quality management and compliance.

Our quality management systems are certified according to the standards that apply to the products we manufacture. XVIVO Perfusion complies with the regulations that apply on markets where our products are sold. Certification includes ISO 13485 and MDSAP (Medical Device Single Audit Program) for compliance with standards and legal requirements on markets for medical technology products in Australia, Brazil, Canada and the US.

### Following up product performance

In order to continuously deliver improvements and benefits to customers, we focus on design and quality control, audits, management reviews, supplier management and following up on the products we have launched and sold.

Our product development process ensures that customer needs are satisfied and that safety standards are met. All ideas are evaluated in depth and potential design risks are identified and eliminated or minimized. We use vivisection restrictively in our product development and actively seek to develop alternative test methods. We test our products on animals only when it is required by law. Clinical trials carried out or outsourced are planned and completed in accordance with the ethical principles

indicated in the Helsinki declaration and follow GCP principles (Good Clinical Practice) and applicable legislation and standards.

XVIVO Perfusion continuously monitors processes and products during the production phase to ensure that our products satisfy quality requirements.

We implement continuous improvements in our CAPA process (Corrective and Preventive Action) and conduct extensive investigations of root causes. This is followed up with corrective measures aimed at solving problems and preventing repeat occurrences. We follow up compliance with the quality management system in our internal audit process. We are also subject to external auditing, which drives improvements.

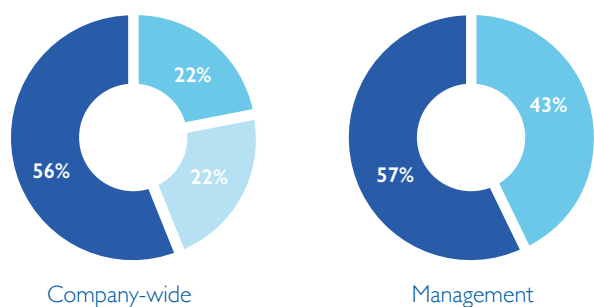
The company's quality management system is reviewed at management level and is organization-wide. The efficiency of our quality management system is analyzed in the review process. We identify areas of improvement and introduce necessary measures when we do not meet our quality targets and demands.

All our suppliers are evaluated to ensure that they meet our quality requirements. When necessary, we conduct on-site inspections based on a risk assessment. We require all suppliers to accept and adhere to our supplier demands.

After a product has been launched, we monitor progress in clinical follow-up and risk management processes, and aftermarket follow-up. We review how our products are being used to ensure that they satisfy customer needs. We investigate all customer complaints relating to our products. Customer satisfaction is measured regularly in surveys to ensure that our products meet customer expectations. We use this feedback and the lessons learned from it to continuously adapt and improve our products.

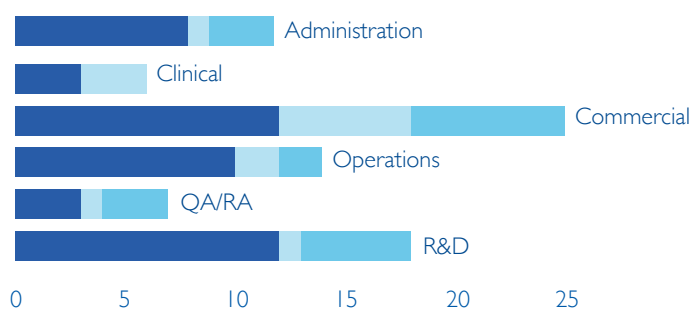
Training aimed at our customers and distributors ensures the safe and effective use of our products. We offer training and workshops at our customers' clinics and in our premises.

### NEW EMPLOYEES 2020



■ New employees ■ New employees via acquisitions ■ Other

### NEW EMPLOYEES BY FUNCTION INCL. ACQUISITIONS



■ New employees ■ New employees via acquisitions ■ Beginning of year

## How we conduct clinical trials

All clinical trials that XVIVO Perfusion carries out or outsources are planned and completed in accordance with the ethical principles indicated in the Helsinki declaration and follow the GCP principles (Good Clinical Practice) and applicable legislation and guidelines.

XVIVO Perfusion undertakes to carry out clinical trials in accordance with applicable local regulations and international legal requirements. These include 95/46/EG (on the protection of individuals with regard to the processing of personal data and on the free movement of such data) and ISO standard 14155 (Clinical investigation of medical devices for human subjects — Good clinical practice).

To ensure that patient rights, safety and wellbeing are protected, that reported data is reliable and robust and that the conduct of clinical trials corresponds to MDR 2017/745, XVIVO Perfusion undertakes to subject itself to sufficient oversight of all clinical operations. The extent of such oversight is determined on the basis of assessments that include all the characteristics of the clinical trial.

## Human rights

XVIVO Perfusion promotes diversity and equality. Equal treatment and equal opportunity shall apply to all regardless of gender, gender identity, ethnicity, religion or faith, disability, sexual orientation and age. XVIVO Perfusion does not accept any form of mental or physical punishment, threat of punishment, discrimination in connection with job opportunities or employment, bullying in the workplace or sexual or other forms of harassment.

XVIVO Perfusion shall not utilize forced labor and/or child labor in any part of its operations and shall ensure that business partners act in the same manner.

It is critical that XVIVO Perfusion's suppliers maintain the highest standards in terms of regulatory compliance, human rights, working conditions and environmental considerations. All our major suppliers are obliged to follow our Code of Conduct.

## Our contribution to society

In addition to the values that XVIVO Perfusion's products generate, our primary social contribution comes from our extensive research work. In 2020, approximately 60 percent of revenue was reinvested in research and development.

One example of significant advances resulting from XVIVO Perfusion's development work is our offering in machine perfusion of lungs, liver and kidney. Clinical studies show that these products allow more donated organs to be used for transplantation. This gives more people the opportunity to live longer and more active lives, which ultimately increases quality of life and generates socioeconomic benefits.

XVIVO Perfusion supports and collaborates with organizations and associations that work to increase organ donation



and improve the lives of the families affected. In Sweden, XVIVO Perfusion supports MOD (More Organ Donation) and Jontefonden, as well as other funds. In the US, we have recently made donations to institutions such as Transplant House in Philadelphia and Donate Life Float.

## BUSINESS ETHICS AND ANTI-CORRUPTION POLICY

XVIVO Perfusion's operations are based on the fundamental principle that good business ethics must prevail in all business operations and relationships with our customers, business partners and the authorities.

We fully comply with anti-trust legislation and all applicable competition laws regulations in force in the countries where we operate.

XVIVO Perfusion does not accept that bribes – regardless of form, method or purpose – are offered, demanded or accepted. No employee is permitted to demand or accept gifts, entertainment or personal services that could reasonably be considered to influence business transactions or that contravene applicable legislation or business practice. Our business ethics also mean that we do not take a political standpoint. Therefore, our funds or assets are not used to support political campaigns or candidates, or otherwise provide services for political purposes.

## ENVIRONMENTAL RESPONSIBILITY

XVIVO Perfusion's environmental impact is primarily derived from the production of and materials for our products (mainly single use articles), and transports and travel (mainly by air).

We strive to rationalize our processes and transport in dialog with our customers and suppliers. In addition, we offer a global product range and extended durability for our products, which contributes to reducing the environmental impact. Because XVIVO Perfusion's employees are based on several different continents, we hold digital internal meetings as far as possible and only travel when necessary.

# ENORMOUS NEED FOR NEW ORGANS

In 2019, approximately 163,000 organ transplants were performed from more than 38,000 donors. Although the number of donors is increasing it is not enough - according to the WHO the number of transplants performed only corresponds to 10 percent of the need. Because of the acute shortage of organs, patients are subject to a strict selection process before being added to the waiting list to receive a new organ.

Over 250,000 people in the US and Europe are waiting for a new organ. Most people are waiting for a kidney, many for a liver and some for lungs or a heart. The background could be a congenital and potentially hereditary condition, but also exposure to tobacco, alcohol or infectious diseases. The people waiting for new organs are seriously ill and are expected to live for less than two years. Approximately 25 percent of the people waiting for new lungs or a new heart die while waiting for the new organ or are removed from the waiting list because they become too ill to undergo a transplant.



## LUNG TRANSPLANTATION

Lung transplantation is the last option for treating a patient with terminal lung disease, where other medical or surgical options are excluded and the expected survival rate is less than 2 years without a new organ.

**Causes.** The top four underlying diseases that cause a patient to need new lungs are mainly chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF), idiopathic pulmonary fibrosis (IPF) and pulmonary arterial hypertension (PAH).

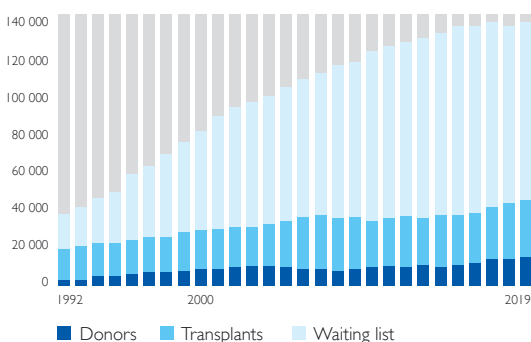
Common causes of COPD are tobacco smoking and exposure to various types of pollutants. The WHO estimates that 200 million people suffer from COPD and the disease causes 3 million deaths each year. Cystic Fibrosis is a progressive disease that causes abnormal mucus formation, which affects the lungs and digestive organs in particular. The thick mucus leads to significant and chronic respiratory infections often requiring antibiotic and

nebulized treatment and hospitalization. These infections result in progressive loss of lung function and decreased survival and is marked by acute worsening of symptoms often requiring hospitalization which are called "pulmonary exacerbations." IPF is a disease progressively worsening scar tissue in the lungs, whereby the lung cannot take in enough oxygen. Pulmonary arterial hypertension is a life-threatening progressive disorder where the pressure in the pulmonary artery is too high, thereby destroying blood vessels in the lungs.

**Background.** The first lung transplant was performed in 1963, but it took until 1982 for the first lung transplant patient to live long enough to leave the hospital. Survival after a lung transplant has increased as surgical techniques have been refined, immunosuppressive drugs have been introduced, aftercare improved and preservation solutions and techniques become more advanced. Today, lung transplantation is an established standard treatment for patients with terminal lung disease.

**Advances.** Although the survival rate after lung transplantation is relatively good – about 80 percent after the first year – lung transplantation is carried out to a limited extent. The main reason is a lack of organ donors. Another limitation is that the lungs often suffer from rapidly impaired function once the donor dies. In as much as 80 percent of cases, the lungs are in too poor a condition to be transplanted. With the help of Ex Vivo Lung Perfusion, the proportion of transplantable organs can be increased from 20% to 40%.

## WAITING LISTS IN THE US



**A GROWING GAP BETWEEN THE NEED FOR ORGAN TRANSPLANTATION AND THE AVAILABILITY OF DONATED ORGANS SINCE THE WAITING LISTS ARE GETTING LONGER.**

THE CURVE ILLUSTRATES THE WAITINGLIST SITUATION IN USA.





## HEART TRANSPLANTATION

Heart transplantation is the last option for treating severe heart failure, where other medical and surgical treatment options have been exhausted.

**Causes.** The main causes of heart failure are the destruction of parts of the myocardium after one or more heart attacks, congenital heart defects (usually unicameral hearts), severe heart muscle disease, very high blood pressure and certain metabolic diseases. The prognosis for severe heart failure is very poor and half of patients die within one year of diagnosis. The WHO estimates that cardiovascular diseases (including stroke) cause more than 17 million deaths each year.

**Background.** The first heart transplant was performed in 1967, but the results of the first transplants were disappointing. It was not until the 1980s that heart transplantation was established as a method. Like for those receiving lung transplants, patients that

have received a new heart now live longer as surgical techniques have been refined, immunosuppressive drugs have been introduced, aftercare improved and preservation solutions and techniques have become more advanced. Today, heart transplantation is an established standard treatment for patients with severe heart failure.

**Advances.** While research has led to many advances and better treatments, unfortunately the number of people with cardiovascular disease is on the increase. The cause is unhealthy lifestyles such as smoking, insufficient exercise and unhealthy eating habits.

Nowadays some patients can receive mechanical heart pumps, known as the Left Ventricular Assist Device (LVAD). The heart pump helps the diseased heart and restores blood circulation in the body. These are used as a supplement while awaiting heart transplantation.





## KIDNEY TRANSPLANTATION

Kidney transplantation is the primary treatment for chronic kidney failure. It is possible to transplant kidneys from both deceased and living donors.

**Causes.** The most common causes of chronic kidney failure are diabetes and high blood pressure, although it can also be caused by hereditary kidney disease and kidney inflammation.

People suffering from serious kidney failure, with uremia, require regular dialysis or a kidney transplant to survive. A transplant is often the best treatment, as the patient is able to avoid dialysis, pharmaceuticals and frequent medical check-ups and often feels better. Dialysis is also a very costly life preserving treatment.

According to the WHO, kidney disease is the number 10 cause of death globally. Mortality has increased from 813,000 deaths in 2000 to 1.3 million in 2019. Demand for kidneys far exceeds supply; in the US, there are more than 90,000 people on the waiting list compared to just over 24,000 completed transplants (in 2019).

**Background.** Attempted kidney transplants were carried out in the Ukraine in the 1930s, and the first successful transplantation was completed in 1950. The first transplants between live patients were carried out in the 1950s, and the first successful surgery of this kind was completed in 1954. In that case, the donor and recipient were identical twins, which reduced the risk of immunoreaction. Joseph Murray, one of the surgeons behind the transplant, was awarded the Nobel Prize in medicine in 1990. Today, some 62,000 kidney transplants from deceased donors are carried out each year in more than 2,200 clinics.

**Advances.** Advances in kidney transplantation have ensured better care of donated organs, surgical techniques and anesthesia. Also, the introduction of immunosuppressive pharmaceuticals, which prevent and treat organ rejection, has been critical to progress. The next important step is to increase the number of kidneys available for transplantation through new machine perfusion techniques.



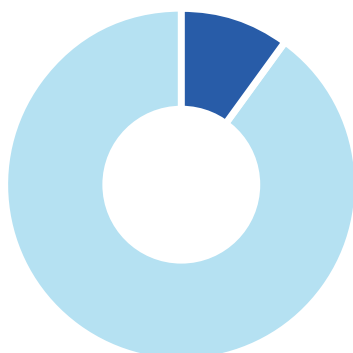
## LIVER TRANSPLANTATION

Liver transplant is a treatment option for terminal liver disease and acute liver failure.

**Causes.** There are many causes of liver disease – the most common in the western world is over-consumption of alcohol. The causes of acute liver failure vary between and within different parts of the world. Viral hepatitis was previously the most common cause in Europe and the US, although pharmaceuticals (such as overdoses of paracetamol) are now behind most cases of liver failure. In many patients, it is not possible to determine the cause of liver failure.

**Background.** Liver transplants were first trialed in dogs in the 1950s and the first trials in humans were carried out in the 1960s. In 1967, Thomas E. Starzl, a pioneer in modern transplantation, successfully transplanted a liver into a girl with liver cancer who survived for one year before dying from metastasizing disease. Liver transplantation was an experimental treatment in the 1970s and became standard in the 1980s, largely due to the introduction of ciclosporin, which is an immunosuppressant. Today, some 28,000 liver transplants from deceased donors are carried out each year in close to 1,000 clinics.

**Advances.** Advances in liver transplantation have ensured better care of donated organs, surgical techniques and anesthesia as well as optimizing the timing of transplantation. All this has ensured that the one-year survival rate now exceeds 90 percent. The next important step is to increase the number of livers available for transplantation through new machine perfusion techniques.



**>160 000 ORGANS  
TRANSPLANTED PER YEAR,  
REPRESENTING  
~10% OF THE NEED\***

\*WHO estimate





XPS (XVIVO Perfusion System) enables data registration of lung values throughout the EVLP procedure, which provides a basis for analysis and evaluation ahead of the final clinical decision regarding use of the lung.





“ONE SINGLE  
DONOR CAN  
SAVE UP TO  
**EIGHT PATIENTS**”

# ORGAN DONATION

## – THE GIFT OF LIFE

One of the biggest challenges in the field of transplantation is the shortage of suitable organ donors. If the availability of donated organs were greater, more patients could receive transplanted organs and thus have the opportunity to live longer and better lives. An individual donor can save up to eight people by transplanting the heart, lungs, kidneys, liver, pancreas and small bowel.

### Donation after primary brain damage

Most of the organs that are transplanted come from brain-dead donors (donation after brain death, DBD). Brain death means that the patient is declared dead based on neurological criteria and that the person is dead medically and according to law. The introduction of the definition of brain death has been critical to organ donation and transplantation surgery.

In DBD donation, the heart maintains circulation while a respirator oxygenates the blood, which facilitates the transplantation process. There is also time to talk to relatives and to take care of the organs.

### Donation after circulatory death

DBD donation is still the first choice but the acute shortage of brain-dead donors has led to the re-introduction of donation after heart death/circulatory death (DCD). This has also meant that more people have been offered the opportunity to donate organs after their death.

In the case of DCD, the donation process must be much faster from when circulation stops until the organs are taken care of. If the process takes too long, the organ becomes unusable. Uncertainty relating to the function of these donated organs is usually higher.

### Expanded criteria donation

Another possibility that an increasing number of clinicians are investigating is whether methods can be found to take advantage of organs that have previously been abandoned, known as expanded criteria donation. This is possible thanks to improved technology and preservation solutions.

Organs considered marginal may come from older donors, infected donors (such as Hepatitis B&C and HIV) or donors with high BMI, diabetes or high blood pressure. The inclusion of marginal organs in the donation process has made the decision

of whether or not to accept an organ more complex than previously. However, for most patients waiting for an organ the benefit outweighs the risk of receiving a marginal organ.

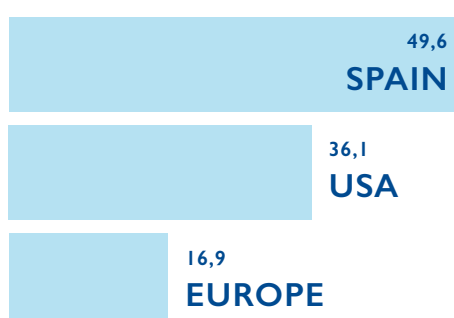
### Major differences in donation frequency

Different countries have different success rates in terms of organ donation. This is visible in the donation frequency, i.e. the number of donations per capita.

#### The Spanish model:

*There are many factors that contribute to Spain having more than twice as many organ donors compared to Sweden in relation to population. In Spain, it is assumed that a person is in favor of donating their organs unless they explicitly state the opposite. Sweden has a similar system but has not achieved the same result. The reason for the success is probably that Spain established a national transplantation organization (ONT) in 1989 that improved coordination of the donation and transplantation process. Early on, Spain introduced donor managers (often intensive care physicians) in hospitals who identified potential donors in intensive care units, on wards and in emergency departments at an early stage. ONT has also trained more than 15,000 healthcare workers in the donation process. Another factor that has led to high donation frequency is that donors who have died of heart death, and organs from older donors, are accepted to a greater extent than in many countries (more than 10 percent of donors are over 80 years of age at present).*

### ORGAN DONORS PER MILLION INHABITANTS



Source: Data from WHO-ONT Global Observatory on Donation and Transplantation 2019.

# OFFERS IN ALL FOUR MAJOR ORGAN AREAS

XVIVO Perfusion's core competence and offer is caring for organs outside the body, from being removed from a donor to transplantation. This year's acquisition of Dutch company Organ Assist expands XVIVO Perfusion's offering to include products for storage and evaluation of kidney and liver.

## THORACIC OFFERING

### Lung transplantation

Today, donated lungs can be taken care of in a static cold preservation process, or in combination with evaluation during warm perfusion. XVIVO Perfusion offers products for cold static storage and warm perfusion.

### Products for cold static preservation

Cold preservation means that the organ is cooled by major blood vessels being circulated with a cold solution. The lungs are then stored in a solution in bags on ice. Cooling slows metabolism and thus preserves organ function.

**Products.** XVIVO Perfusion main product for cold preservation is PERFADEX Plus. The product has been the standard treatment in lung transplantation for 20 years.

**How it works.** In addition to lowering the temperature and decreasing metabolism, PERFADEX Plus also flushes out donor blood that contains substances that can damage the lungs. After that, the lungs are cooled during transport to the recipient hospital and until transplantation. In a cooled state, lungs can normally be stored for 6-10 hours outside the body and transplanted with good results.

**Advantages.** PERFADEX Plus is the standard for cold preservation of donated lungs – around 90 percent of all lung transplants

are carried out using PERFADEX Plus, and so far more than 50,000 transplants have been carried out with PERFADEX/PERFADEX Plus.

Cold preservation is an established and safe method. However, one limitation is that it is not possible to evaluate donated lungs in the cooled state. Since lung transplantation is a complicated and life-changing procedure for the patient, surgeons refrain from using donor organs where they are uncertain of the quality. This means that up to 80 percent of donated lungs are rejected and not used for transplantation. Accordingly, XVIVO Perfusion focuses on warm perfusion.

### Products for warm perfusion

Warm perfusion of lungs, or normothermic ex vivo lung perfusion (EVLP), means that the organ is heated to body temperature outside the body and circulated with a solution.

**Products.** XVIVO Perfusion offers three methods and systems for EVLP:

- XPS (XVIVO Perfusion System), an integrated machine with all components required for normothermic EVLP
- XVIVO LS, a machine for evaluating lungs with EVLP
- Lung Assist, a machine for evaluating lungs with EVLP and
- Manually with the help of STEEN Solution and the accessories XVIVO Organ Chamber and XVIVO Lung Cannula.



## THE XVIVO PRODUCT RANGE



### Machine perfusion platforms



XPS



Lung Assist

### Disposables for machine perfusion



XPS Disposable Lung Kit



STEEN Solution

### Static preservation



PERFADEX Plus



XVIVO Silicone Tubing Set



### UNDER EVALUATION IN CLINICAL TRIALS



XVIVO Heart Device



XVIVO Disposable Heart Set



Kidney Assist Transport



Kidney Assist



Liver Assist



Donor Assist

Since October 2020 we also offer Lung Assist for EVLP which has been developed by Organ Assist.

Both XPS, XVIVO LS, our manual system and Lung Assist are used with STEEN Solution. STEEN Solution is XVIVO Perfusion's solution for warm perfusion of donated lungs. XPS and STEEN Solution are approved on all major markets. XVIVO LS and Lung Assist have CE-marking.

**How it works.** In normothermic EVLP, donated lungs are circulated with STEEN Solution and heated to body temperature. During the process, the lungs are connected to a pump for circulation and to a ventilator to simulate breathing. Normothermic EVLP recreates a non-harmful environment, similar to that in the body (in vivo), which gives the lung and its cells the opportunity to recover.

**Advantages.** Several studies show that patients who received lungs that were initially deemed to be marginal, but were judged to be acceptable after STEEN Solution treatment, achieved equivalent results as patients that had been transplanted with standard lungs. Our method has potential to increase utilization of donated lungs from around 20 to 40 percent.

It has been clinically demonstrated that EVLP with the STEEN Solution method extends the time that lungs can be stored outside the body for up to 24 hours in some cases, compared to 6 to 10 hours for the standard method. This provides clinics with more opportunities to find the right recipient and to plan and streamline their work.

**Extensive studies of EVLP with the STEEN Solution method**

**HELP study.** In 2012, Toronto published the results of 50 lung transplants performed after EVLP. The conclusion was that transplantation of donated "high-risk" lungs is safe after 4 hours of EVLP and produces equivalent results as conventional transplantation. EVLP also increased the use of donated lungs.

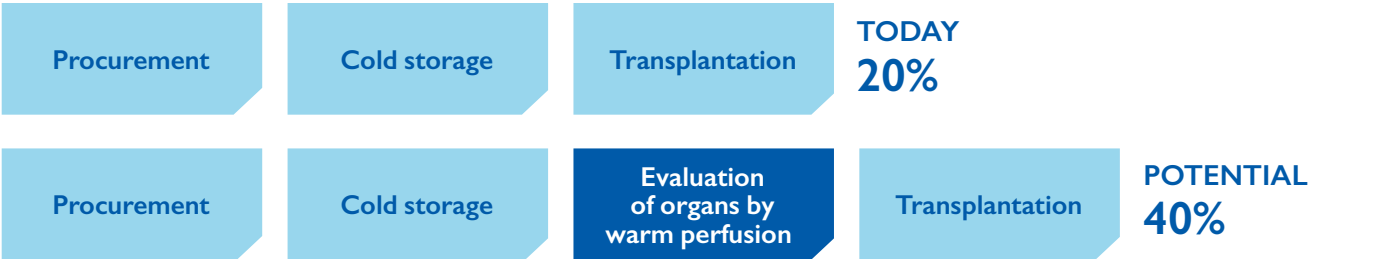
**THE NOVEL/NOVEL Extension study.** The first part of the NOVEL study took place between 2012 and 2014 in the US, and formed the basis for XVIVO Perfusion's application for HDE approval in the US. The study was designed to show that EVLP can safely increase the number of usable lungs from the donor pool. The study compared the clinical results after transplantation of lungs that had undergone warm perfusion after initially being deemed unusable, with a control group of lungs deemed useful. The NOVEL study then continued (NOVEL Extension) and the inclusion of 220 patients was completed in 2017, which formed the basis of the PMA application submitted in 2018 and subsequently approved in 2019. Data from the NOVEL Extension study demonstrates that EVLP with XPS and STEEN Solution is safe and effective.

**The Vienna study.** In a study conducted in Vienna, cold static preservation was compared with PERFADEX and cold static preservation with PERFADEX followed by EVLP on so-called standard lungs. The study was the first of its kind to examine the effect of EVLP in a randomized prospective design. The study demonstrated no statistically reliable difference between the groups, but showed a trend towards minor primary graft dysfunction (PGD) in the EVLP group.

**MORE LUNGS AVAILABLE WITH WARM PERFUSION**

Today, about 20 percent of all donated DBD lungs can be used. The use of warm perfusion allows about 40 percent of all donated DBD and DCD lungs to be utilized, including marginal lungs.

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



## THE ADVANTAGES OF THE STEEN SOLUTION METHOD

PROBLEM	STEEN SOLUTION	ADVANTAGE
<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 waiting list are given the opportunity to receive transplantation</li> </ul>
<ul style="list-style-type: none"> <li>&gt;70 percent of sampled lungs are deemed to be untransplantable</li> </ul>	<ul style="list-style-type: none"> <li>Functional testing, perfusion of organs outside the body, possible reconditioning effect</li> </ul>	<ul style="list-style-type: none"> <li>More 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 heart-dead donors 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 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 (normally night time) 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 more time to plan procedures</li> </ul>	<ul style="list-style-type: none"> <li>Daytime surgery, reduces burden on healthcare services</li> </ul>
<ul style="list-style-type: none"> <li>High total cost of emergency surgery 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 more time to plan procedures</li> </ul>	<ul style="list-style-type: none"> <li>Lower total cost due to better opportunity for healthcare planning</li> </ul>



**"NEW  
METHOD  
COMING:  
NON-ISCHEMIC  
PRESERVATION  
(NIHP)"**



## HEART TRANSPLANTATION

Today, donated hearts are stored using cold static preservation. XVIVO develops methods for preservation through oxygenated perfusion of hearts (non-ischemic heart preservation, NIHP).

### New method coming: non-ischemic heart preservation (NIHP)

**How it works.** In connection with conventional heart transplants, the lack of circulation and oxygen supply during transport of the donor heart can lead to poorer clinical results. XVIVO Perfusion's new technology means that the heart is circulated during transport with the help of a machine and a patented solution that provides oxygen and important substances. The technology is patented and has been developed alongside Igelösa Life Science and Professor Stig Steen, and has been commercialized by XVIVO Perfusion.

In animal trials, non-ischemic, that is oxygenated, heart preservation means that donated hearts can be successfully stored outside the body (ex vivo) for up to 24 hours.

**Advantages.** NIHP generates a significantly longer window compared to the four hours provided by the standard method of cold preservation. The time outside the body is directly correlated to the survival of the recipient. This is even more evident if the donor is older - then the time outside the body should not exceed 2 hours. The time factor limits the distance a heart can be transported and reduces the ability to find the most suitable

recipient. With a method that allows longer storage outside the body while waiting for transplantation, more hearts could be transplanted, while reducing the cost of logistics and transport.

**Status.** XVIVO Perfusion's heart project is our highest priority and is in the early clinical phase. Towards the end of the year, the first patient was transplanted within the framework of our European heart preservation study. During the year, the scientific journal Nature Communications published an article describing the initial finding of an ongoing study of our technology for heart preservation at Skåne University Hospital. The study shows that the technology is safe.

In addition to the European study, XVIVO Perfusion is planning a multicenter study in the US, and one in Australia. The objective is to investigate whether the new technology can improve clinical results and reduce complications after heart transplantation. The overarching purpose is to make more hearts available and to transplant them with good results. The clinical documentation from the planned studies will form the basis for an application for regulatory approval on all major markets.

### Pre-clinical and clinical experience of NIHP

In pre-clinical studies on pigs conducted by Professor Stig Steen and his research team, the new method for storing donated hearts for up to 24 hours has been shown to be safe.<sup>1</sup>

A research team in Munich, under the leadership of Professor Bruno Reichart, has published data from experiments in xenotransplantation, i.e. transplantation between species<sup>2</sup>. XVIVO Perfusion's non-ischemic heart preservation technology was used to transplant hearts of genetically modified pigs into baboons. For the first time, recipients of donated hearts achieved long-term survival in the experiments. In future, the hope is that pig hearts can be used for human heart transplantation, which would address the organ shortage. Our technology and solution has been chosen for this promising research project.

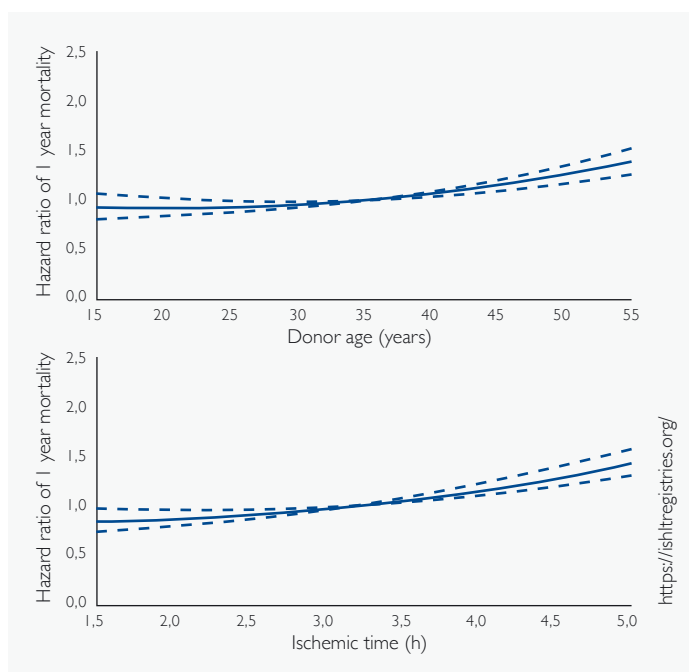
Skåne University Hospital in Lund successfully completed the first clinical heart transplants using the new XVIVO Perfusion technology in a recent study in patients<sup>3,4</sup>. The results of the first six heart transplant patients in Lund indicate that the method is safe to use in humans.

1. Steen S, et al. Safe orthotopic transplantation of hearts harvested 24 hours after brain death and preserved for 24 hours. *Scand Cardiovasc J*. 2016 May 3; 50 (3): 193-200.

2. Längin M, et al. "Consistent success in life-supporting porcine heart xenotransplantation". *Nature*. 2018 Dec; 564(7736): 430-433.

3. Nilsson J, Conference Paper in The Journal of Heart and Lung Transplantation 37(4):S13 · April 2018.

4. Nilsson, J et al. "A nonrandomized open-label phase 2 trial of nonischemic heart preservation for human heart transplantation". *Nat Commun* 11, 2976 (2020).



## ABDOMINAL OFFER

With the acquisition of Organ Assist, XVIVO Perfusion has extended its offer to include the abdominal area. From the end of the year, we offer machines for perfusion of liver and kidney. The machines enable preservation, reconditioning and evaluation of organs.

Today, kidneys can be transplanted after static cold storage, or alternatively after machine perfusion. Machine perfusion can be normothermic (maintains normal body temperature; 35–37°C), sub-normothermic (below normal body temperature; 20–34°C) or hypothermic (significantly below normal body temperature; 0–12°C).

**Products.** XVIVO Perfusion offers the following products for oxygenated machine perfusion in the abdominal area:

- Kidney Assist Transport, a portable machine for hypothermic preservation of kidneys during transportation for up to 24 hours.
- Kidney Assist, a machine for hypothermic reconditioning and normothermic evaluation of kidneys for up to 6 hours.
- Liver Assist, a machine for hypothermic reconditioning and normothermic evaluation of liver for up to 6 hours.
- Donor Assist, machine for isolated oxygenated normothermic perfusion of organs in the deceased donor's body, during the donation surgery.

**How it works.** The technology the machines are based on is essentially the same, but the machines are adapted as different organs require different treatment.

All machines for perfusion of kidney and liver are based on regulating oxygen, temperature and flow. The machines can be used in several different phases; during the donation process, during storage and transport and immediately prior to transplantation.

The machines for kidney and liver are modular, with at least one pump, oxygen supply and a set of single-use articles for each unit.

One extra pump, a heating unit and a trolley or cool box can be added, depending on which organ the machine is being used for.

**Advantages.** The most important function and advantage is that the machines for kidney and liver enable non-ischemic (oxygenated) perfusion. Several research studies have shown that oxygenated perfusion solution has positive effects on organs and clinical results.

The machines also offer temperature control and for liver and kidney we are unique in the world to offer machines for both cold and warm perfusion.

Furthermore, the machines have one or several pumps that create a pulsating flow and thus provides the organs with circulation and microcirculation. This occurs regardless of pressure.

Finally, the pressure is also variable. The machines have a number of pre-settings, to ensure that the pressure is optimal for the relevant perfusion temperature and the organ treated.

Overall, XVIVO Perfusion's machines for kidney and liver ensure better quality of donated organs, which means that more donated organs can be transplanted and fewer are rejected.



Arjan van der Plaats, Research and Development Director in the Abdominal business area and founding partner of Organ Assist.

An article published in scientific journal *The Lancet* in November 2020 shows that oxygenated perfusion of kidneys before transplantation has a significant impact on outcomes in the first year after transplantation: lower risk of terminal kidney failure, improved kidney function and less cases of rejection of the kidney compared to only cold perfusion. The randomized study, using kidneys from donors aged 50 or above and which were donated after circulatory death, was carried out in 19 European transplantation centers and included 212 patients.

Jochmans I, et al. "Oxygenated versus standard cold perfusion preservation in kidney transplantation (COMPARE): a randomized, double-blind, paired, phase 3 trial", *The Lancet*, November 2020





Study where Kidney Assist Transport was used shows improved survival of transplanted kidneys after cold machine perfusion with added oxygen.

# STRONGER POSITION ON A GROWING MARKET

In 2019, approximately 163,000 organ transplants were performed from more than 38,000 donors. North America is the largest market in the world for organ transplantation, followed by Europe, while China is a rapidly growing market. XVIVO Perfusion has strengthened its position as a result of the acquisition of Organ Assist. In addition, there is significant unutilized potential – we expect to expand our market, mainly through new methods for preservation, evaluation and reconditioning of lungs, hearts, kidneys and livers.

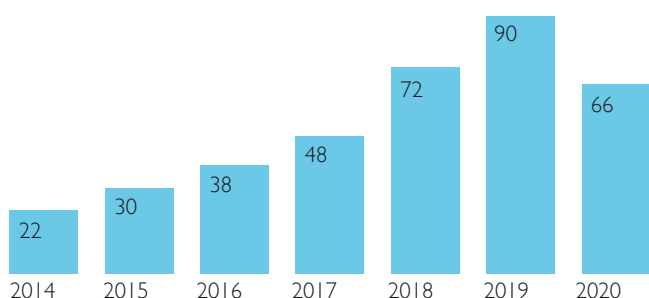
## TRENDS AFFECTING US

### TREND I: Growing and aging population

The global population continues to grow, and the proportion of elderly people is rising. According to the UN, 1 in 6 people are expected to be over the age of 65 in 2050, compared to 1 in 11 in 2019. In addition, an increased proportion of life will be spent above the age of 65.

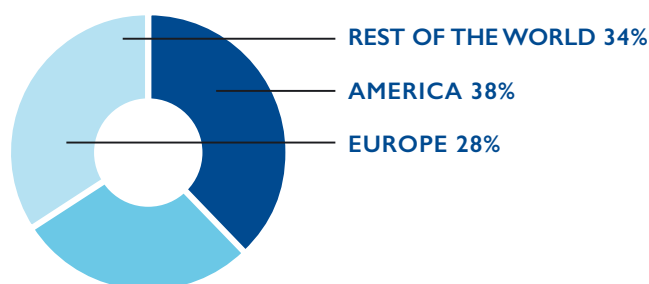
**Potential for XVIVO Perfusion.** An increased proportion of elderly people in the population is an important factor affecting supply and demand for organs for transplantation. Older patients can both donate and receive organs – age is no longer a significant contraindication. In the past, transplantation teams have been reluctant to receive organs from donors above the age of 55 due to concerns about poor outcomes for the recipient. The shortage of standard organs, coupled with the technology for evaluating organs, opens up the possibility of older donors and more donated organs.

## SALES MACHINE PERFUSION EXCLUDING CAPITAL GOODS\*, SEK M



\* Sales warm perfusion excluding capital goods is sales of STEEN Solution and other sterile disposables used in lung evaluation.

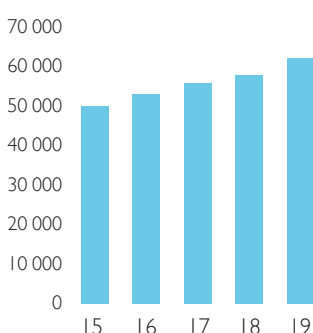
## LARGEST MARKETS



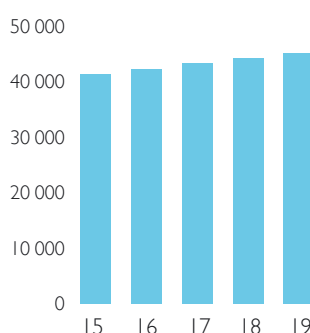
## DISTRIBUTION OF LUNG TRANSPLANTATION PERFORMED 2015-2019

Source: GODT, OPTN and company's own analyses

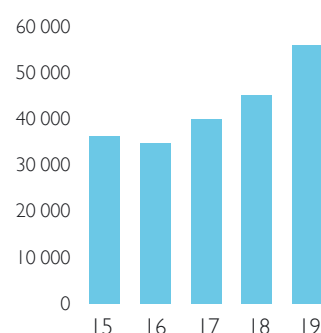
### AMERICA



### EUROPE



### REST OF THE WORLD



## TREND 2: Increase in chronic disease

Chronic disease (or non-contagious disease, NCD) causes 41 million deaths annually, representing 71 percent of all deaths globally. 52 million people are expected to die from chronic disease in 2030.

Cardiovascular disease causes most deaths (17.9 million), followed by cancer, pulmonary disease and diabetes. Four main factors increase the risk of dying from a NCD: tobacco, an unhealthy diet, insufficient physical activity and harmful alcohol consumption.

**Potential for XVIVO Perfusion.** NCD increases the need for organ transplantation and this is where XVIVO Perfusion can make a significant difference. For example, COPD (chronic obstructive pulmonary disease) is the most common reason for patients needing lung transplants. Over 200 million people suffer from COPD and the disease causes 3 million deaths each year. In addition, COPD is socioeconomically costly, which also increases demand for transplantations.

## TREND 3: Increased healthcare expenditure

The healthcare sector continues to outgrow the global economy generally. In 2016, expenditure totaled USD 7.5 Bn or 10 percent

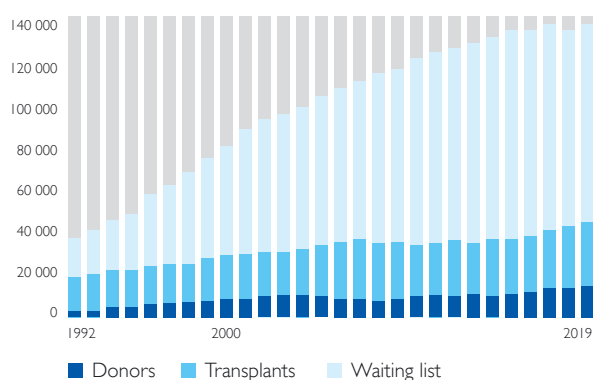
of global GDP. Healthcare expenditure in low and middle-income countries is growing faster than in high-income economies, although the gap is still significant – the 20 percent of the global population living in high-income countries generates 80 percent of healthcare expenditure. A shift is also underway in terms of healthcare funding, away from privately financed/cash payment and towards publicly financed healthcare.

**Potential for XVIVO Perfusion.** Many transplants tend to coincide with higher total healthcare expenditure and a low proportion of privately financed. Increased healthcare expenditure and a higher proportion of public financing is expected to benefit XVIVO Perfusion.

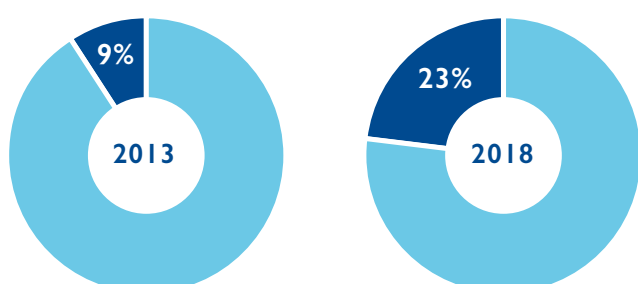
## Impact of the Covid-19 pandemic

The Covid-19 pandemic immediately impacted activity in donations and transplantations globally. The extent of the decline was closely related to the effect of the pandemic on intensive care on each market. Many clinics decided to limit transplantation to emergencies. At a later stage, the US, the EU and other national authorities decided that organ transplants must continue as they represent a life-saving treatment for patients without other options. Transplantation activity has now slowly started to return to more normal levels.

## WAITING LISTS IN THE US

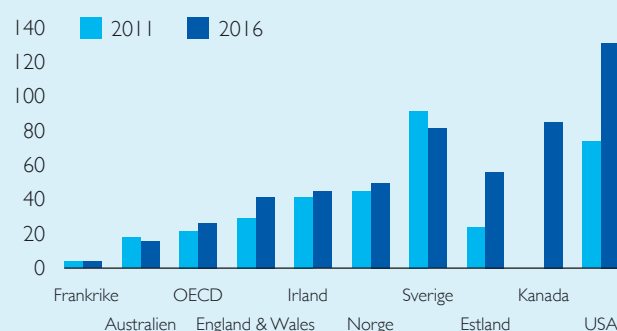


## SHARE OF DONATION AFTER CIRCULATORY DEATH



## THE OPIOID CRISIS LEADS TO MORE ORGAN DONORS

Opioid-related deaths per million inhabitants for selected OECD countries, 2011-2016\*\*



**THE OPIOID CRISIS** According to the U.S. Centers for Disease Control and Prevention (CDC), more than 67,000 people died as a result of overdoses in 2018 in the United States, with two-thirds related to opioid use. According to an OECD report from 2019, there is an increase in opioid-related deaths in Europe as well, and Sweden is one of the countries most affected. The number of opioid-related deaths in Sweden has more than doubled between 2011. An effect of . One effect of the opioid crisis is that more people become organ donors. The reason is that an overdose of opioids can cause respiratory arrest and lead to suffocation and brain death. In 2017, one in eight donors in the United States had died as a result of opioid overdose compared to one in 100 in 2000.

\*\* Source: EMCDDA and OECD (2019), Addressing Problematic Opioid Use in OECD Countries



## OUR MARKET

Of transplanted organs, kidney and liver represent the absolute majority; 64 and 24 percent respectively. Heart represents six percent and lung four percent. Transplantation of other organs is very unusual (pancreas and small bowel) or does not occur at all.

North America is the world's largest market for organ transplants – almost half of all lung and heart transplants occur there.

### Lung

**Total market.** In 2019, some 6,700 lung transplants were reported, of which 41 percent in the US, 35 percent in Europe and 24 percent in the rest of the world. The 10 most active countries represent 81 percent of the total market.

According to GODT (Global Observatory on Donation and Transplantation) there are 383 lung clinics, of which we estimate that around 250 are active.

**Position and competitors.** XVIVO Perfusion is world-leading in the cold preservation of lungs and PERFADEX Plus is currently used in over 90 percent of all lung transplantations. French Institute Georges Lopez (IGL) offers Celsior for cold preservation of several different organs, including lungs. In addition, there are two generic versions of PERFADEX: Servator P from Italian S.A.L.F. and LungProtect from Polish Carnamedica. In some markets there are locally produced solutions, for example in China and Japan. These competitor products have a combined market share of 5-10 percent. None of these products are approved by the US FDA for the storage of lungs and none are as user-friendly as PERFADEX Plus.

For warm perfusion of lungs, OCS Lung from US-based Transmedics offers a CE-marked and FDA-approved machine with associated solution. OCS Lung is used for bilateral lungs only

and with a different protocol than those used with XPS, XVIVO LS and LungAssist, and is used for warm transport of lungs between donors and recipients.

### Heart

**Total market.** In 2019, some 8,600 heart transplants were reported, of which 42 percent in the US, 34 percent in Europe and 24 percent in the rest of the world. The 10 most active countries represent 77 percent of the total market.

According to GODT there are 780 cardiac clinics which has performed heart transplants historically, of which we estimate that around 350 are active.

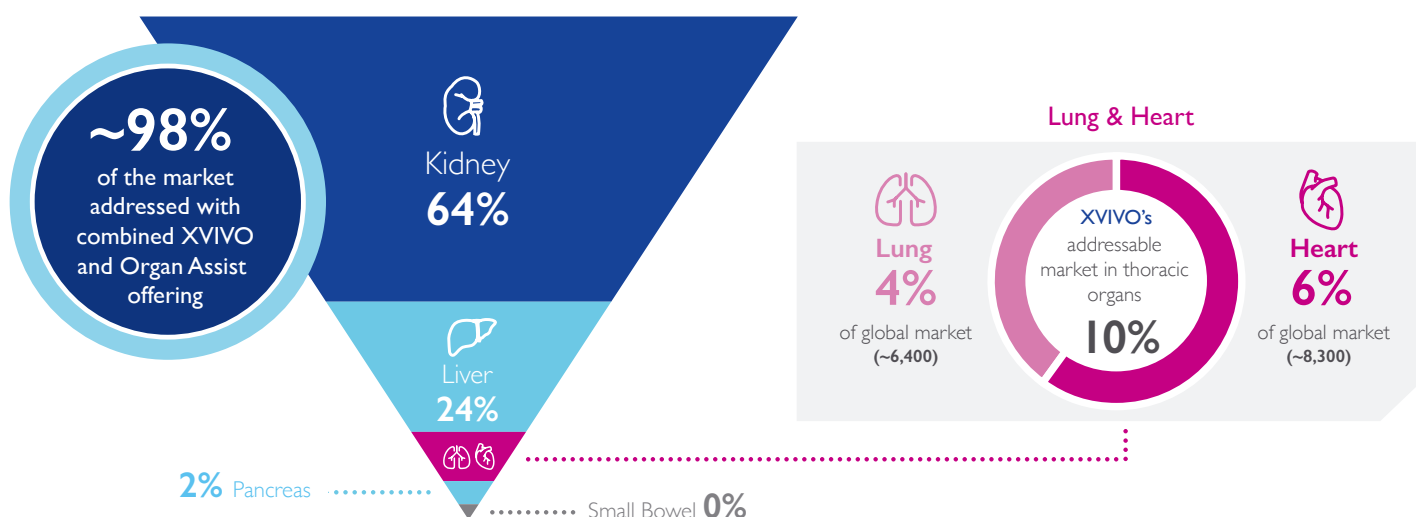
**Position and competitors.** In perfusion of donated hearts, there are two US-based competitors: Transmedics OCS Heart for warm perfusion of beating heart, as well as Paragonix SherpaPak Heart Transport System for cold static storage. OCS Heart is CE-marked and in addition to CE-marking, SherpaPak Heart System has also been approved for sales by the FDA.

### Kidney

**Total market.** In 2019, a total of 98,000 kidney transplants were reported. We are primarily interested in the number of transplants from deceased donors, because that is where XVIVO Perfusion's machines can make the biggest difference. In 2019, 62,000 transplants from deceased donors were carried out, which is 63 percent of all kidney transplants. The US represented 28 percent of these transplants, Europe 33 percent and the rest of the world 30 percent. The 10 most active countries represent 72 percent of the total market.

According to GODT there are 2,529 kidney clinics, of which we estimate that around 2,200 are active.

## TRANSPLANTATIONS PER ORGAN



**Position and competitors.** XVIVO Perfusion's machine Kidney Assist lacks direct competitors. In the area of transport of donated kidneys, there are three products with CE-marking. LifePort Kidney Transporter from Organ Recovery Systems (USA) and RM3 Kidney Perfusion System and Waves from Waters Medical Systems (USA) and IGL (France)

## Liver

**Total market.** In 2019, a total of 34,000 liver transplants were reported, of which 28,000 (82 percent) from deceased donors. The US represented 30 percent of these transplants, Europe 32 percent and the rest of the world 38 percent. The 10 most active countries represent 72 percent of the total market, with the US providing 24 percent.

According to GODT there are 1,181 liver clinics, of which we estimate that around 1,000 are active.

**Position and competitors.** In the area of liver transplants, two competitors offer products with CE-marking: OrganOx of the UK, and Transmedics (USA). Also, Organ Recovery Systems and Bridge to Life (USA) have products waiting for regulatory approvals.

## GROWTH POTENTIAL

The number of donors and transplantations is increasing, and the global market is expected to grow by an average of 5–7 percent annually over the coming five years. However, this only covers 10 percent of the need for donated organs and shortages are acute. This means that it is not the waiting list that determines the size and growth of the market, but how many organs are available for transplantation. We want to contribute to closing the gap between supply and demand and make more organs available for transplantation. This will save lives, have positive socioeconomic consequences and strengthen XVIVO Perfusion's position and results of operations.

The market could be expanded by increasing the donation frequency. XVIVO Perfusion can contribute to market growth by increasing the frequency of use and by expanding on growth markets.

## More donations

Organ shortages can be addressed by increasing the number of available organs to improve the frequency of donations. This can become possible by introducing the concept of presumed consent (i.e. the population is presumed to be in favor of donation unless expressly stating otherwise), improving the infrastructure and logistics surrounding donation and the transplantation process, and raising public awareness.

## More donated organs transplanted

However, the greatest potential for increasing the number is to increase the actual utilization of donated organs. In practice, this means that organs from older donors and marginal organs will need to be accepted for transplantation. With regard to marginal organs, there is significant potential in DCD donation, i.e. taking organs from circulatory dead (DCD) patients, unlike for brain-dead (DBD) patients. DCD is expected to increase significantly more than DBD; 14 percent annually for DCD against 5 percent for DBD. In order to appropriately evaluate, preserve and potentially improve the condition of marginal organs, new technologies are needed for preservation, evaluation and reconditioning—this is where our opportunity lies. After the acquisition of Organ Assist, XVIVO Perfusion is stronger than ever. As a company with a unified offer we are active in all major organs and address approximately 98 percent of the market.

## Potential on growth markets

North America dominates the market for organ transplants (38 percent in 2019), followed by Europe (37 percent in 2018). Asia Pacific represents a significantly smaller share of the market, although the distribution will be very different in just 3–4 years' time. Significant growth is expected in Asia and on other markets, particularly China, India and Brazil.



**“THE NUMBER OF DONORS AND TRANSPLANTS PERFORMED ARE INCREASING AND THE GLOBAL MARKET IS EXPECTED TO GROW IN AVERAGE 5-7 PERCENT PER YEAR IN THE NEXT FIVE YEARS”**

# RESEARCH AND DEVELOPMENT FOR FUTURE TRANSPLANTATIONS

XVIVO Perfusion's overarching strategy is to make more high-quality organs available for transplantation. We do this by developing and offering products for preservation, evaluation and reconditioning of organs. Most of the company's resources are allocated to research in heart and lung transplantation.

## RESEARCH IN NEW INDICATIONS

A proportion of XVIVO Perfusion's research focuses on finding new uses for existing products, particularly STEEN Solution and PrimECC.

XVIVO Perfusion seeks to develop new indications where we have leading-edge competences, and where we see clear synergies with existing areas of sales and significant market potential. In this area, we benefit from several strengths:

- Extensive research experience
- The ability to drive a project from research, through regulatory approval and all the way to market launch
- Established relationships with world-leading researchers and transplantation centers
- Global distribution and market presence

## ONGOING DEVELOPMENT PROJECTS

### Next generation products for heart transplantation

**Projects and potential.** The current limitation on the number of heart transplants mainly relates to the number of available and viable donated organs, and the period a donated heart can survive outside the body. Alongside Professor Stig STEEN, XVIVO Perfusion has developed the next generation of products for preservation (treatment and transport) of donated hearts ahead of heart transplantation. This relates to a combination of solutions and a circulation machine. The purpose is to effectively preserve heart function during transport and to improve transplantation outcomes and give patients the chance to live better and longer lives.

**Status.** XVIVO Perfusion is developing a program of clinical multicenter studies involving nine centers in seven countries in Europe. The studies will form the basis for an application for regulatory approval of the products on all our main markets.

Our European study started in 2020 and the first patient was transplanted at the end of the year. The study will include a total of 202 patients in at least 9 centers in 7 countries. Patients are randomly allocated for transplantation of donated hearts transported with our new method, or stored conventionally, i.e. with the icebox method.

A similar multicenter study is also planned in the US, where XVIVO Perfusion has been granted breakthrough device designation which implies prioritized processing and communication with the FDA. Discussions with the FDA are currently in an intensive phase.

### PrimECC

**Projects and potential.** PrimECC is a fluid developed in collaboration with Professor Stig STEEN. PrimECC is used in heart-lung machines that drive blood circulation and take over the oxygenation of the blood from the heart and lungs during heart surgery. Before the machine is connected to a patient, it needs to be filled with fluid. Today, as a rule, a simple saline solution is used, but the intention is to replace this with PrimECC. PrimECC can protect bodily organs and limit reduced kidney function and other side effects caused by the use of a heart-lung machine.

**Status.** XVIVO Perfusion holds patents for PrimECC on important markets in the US, the EU, China and Japan, and the product already has CE-marking. In 2016 and 2017, a randomized clinical study on 80 patients was completed that showed positive clinical results from the use of PrimECC.

During the year, Sahlgrenska University Hospital included the first patients of a total of 366 in a new study. The patients included in the study are undergoing heart surgery at one of Sweden's university hospitals. More centers are being recruited to the study. XVIVO Perfusion will launch the products after the results of the study have been analyzed.



The heart preservation technique has been developed by Professor Stig Steen at the University of Lund in close collaboration with XVIVO Perfusion.



## Kidney transplantation

**Projects and potential.** Kidneys are no exception – far more kidneys are needed than are available. Studies have shown that transport of kidneys with ongoing perfusion improves the results after transplantation. It has recently been demonstrated that supplying oxygen during perfusion can improve results further. Additionally, evaluating kidney function with warm perfusion can make it possible to use kidneys that would otherwise have been disqualified for transplantation.

**Status.** Towards the end of the year, the scientific journal *The Lancet* published the results of a European study where transplantation of kidneys that had been transported with oxygenated perfusion from Organ Assist were compared with perfusion without added oxygen. A total of 212 patients were included in the study. Patients who received kidney transplants that had been oxygenated during transport with Organ Assist's technology experienced fewer cases of kidney failure in the recently transplanted kidney: 3 percent compared to 10 percent for the control group. In addition, there were significantly fewer cases of rejection of the new kidneys. Our future research will focus on a combination of new perfusion technology and XVIVO Perfusion's solutions.

## ONGOING RESEARCH PROJECTS

### Liver transplantation

**Projects and potential.** It is the same for liver as for other organs – there are significant shortages of transplantable livers.

Several studies suggest that cold oxygenated perfusion of liver before transplantation improves organ quality and reduces the risk of complications. In addition, warm perfusion enables the objective evaluation of donated livers, which can result in more organs that would previously have been disqualified being transplanted.

**Status.** The acquisition of Organ Assist contributed valuable technology and research and development expertise in cold and warm perfusion of liver. This relates to both pre-clinical and clinical studies, of which several clinical studies are in the final phase. The combination of new technology for perfusion developed by Organ Assist and XVIVO Perfusion's solutions will be the focus of our research looking ahead.

### Xenotransplantation

**Projects and potential.** Xenotransplantation is transplantation between species. For us, this relates to transplanting organs from animals, particularly genetically modified pigs, into humans. The method is at the research stage for multiple organs.

**Status.** XVIVO Perfusion's technology for preserving heart function is currently used by two world-leading research teams and has been critical to successful outcomes when genetically modified hearts from pigs are transplanted into primates. During the year, the research teams made important advances – the trials resulted in over three months' survival after transplantation from genetically modified pigs into primates.

# THE SHARE

XVIVO Perfusion's share has been listed on Nasdaq Stockholm under the ticker symbol XVIVO since 2016. The share was listed on Nasdaq First North between 2012 and 2016. One trading block comprises 1 share.

## Share structure

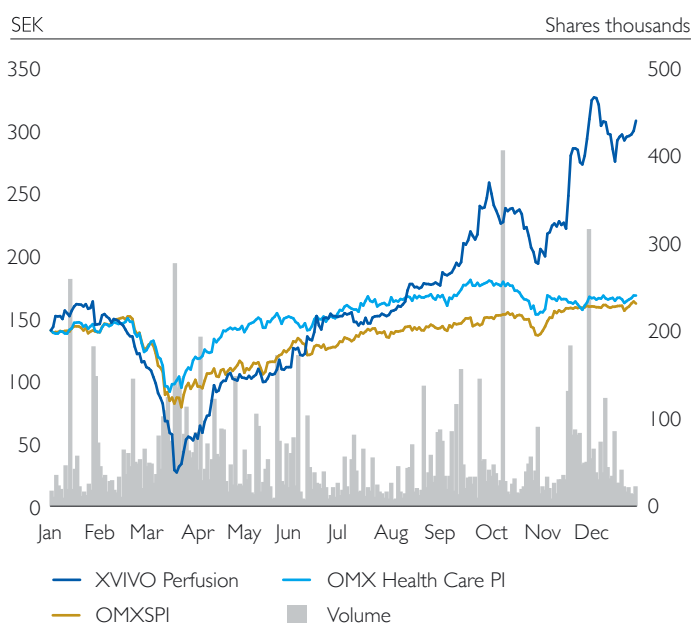
As of December 31, 2020, the share capital of XVIVO Perfusion AB (publ) amounted to SEK 734,025 (679,875) divided into 28,719,136 shares. Trading takes place on Nasdaq Stockholm, Mid Cap. All shares have equal voting rights and have equal rights to a share in XVIVO Perfusion's assets and earnings.

## Share price and turnover

On December 31, 2020, the share price was SEK 314 per share last paid, which represents an increase of 85 (29) percent compared to the closing price on December 31, 2019. OMX Health Care index increased by 15 percent (22) and OMX Stockholm index increased by 13 percent (30) in the same period. At the end of 2020, XVIVO Perfusion's market capitalization amounted to SEK 9,018 million (4,522) based on the latest price paid. The highest price quoted in the year was SEK 330.00 (204.00) and was quoted on December 2. The lowest price quoted in the year was SEK 72.80 (126.40), which was quoted on March 19.

The number of XVIVO Perfusion shares in the year amounted to 11,934,005 (8,708,709) at a value of SEK 2,236 million (1,513). The number of trades was 96,489 (73,125). Share turnover corresponded to 44 percent (33) of the average number of outstanding shares during the year.

## XVIVO PERFUSION'S SHARE IN 2020



## SHARE PRICE 2020

**+85%**

## Dividend policy and dividend

XVIVO Perfusion's Board of Directors believes that the company should have a strong capital base to enable continued growth, both organically and through acquisitions. The Board of Directors and the CEO propose that no dividend be paid for 2020.

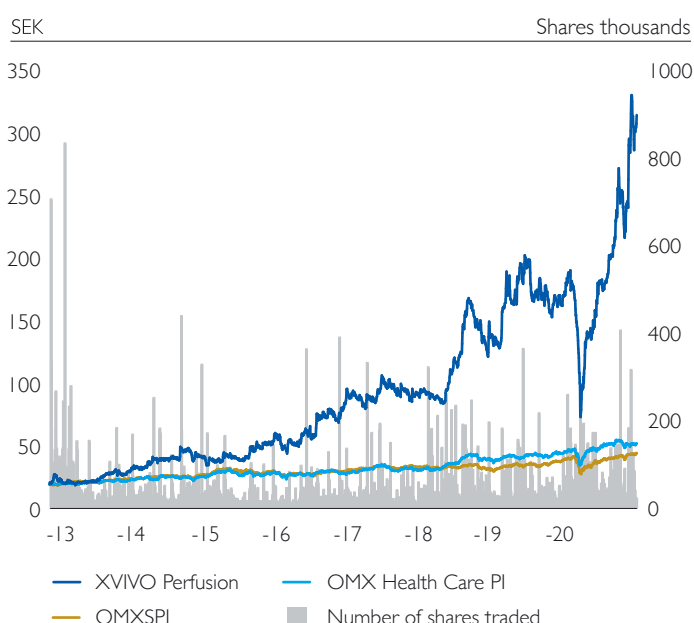
## Ongoing information

XVIVO Perfusion's share is listed on Nasdaq Stockholm, Mid Cap. Continuous information about the company such as press releases, quarterly reports and annual reports can be found on the company's website [www.xvivoperfusion.com](http://www.xvivoperfusion.com).

## Insiders

XVIVO Perfusion is obliged to notify the Swedish Financial Supervisory Authority of persons that have insight into the company. These individuals must notify their holdings of shares and any changes in the holdings.

## XVIVO PERFUSION'S SHARE SINCE LISTING IN 2012



The Board members and the CEO and CFO are considered to have an insider position in XVIVO Perfusion. A full list of individuals with an insider position and their holdings is presented on the company's website [www.xvivoperfusion.com](http://www.xvivoperfusion.com).

### Warrant program

In total, there are 725,000 outstanding warrants in two programs. The 2019 Annual General Meeting resolved to issue a maximum of 351,000 warrants (series 2019/2020) with the accompanying right to subscribe for a maximum of 351,000 new shares to employees of the XVIVO Perfusion Group. Of these warrants, all 351,000 have been subscribed for by employees. The warrant program 2019/2020 gives the warrant holder the right to subscribe for a new share at SEK 278.91 during May 2021.

The 2020 Annual General Meeting resolved to issue a maximum of 408,000 warrants (series 2020/2022) with the accompanying right to subscribe for a maximum of 408,000 new shares to employees of the XVIVO Perfusion Group. Of these warrants, 374,000 have been subscribed for by employees. The warrant program 2020/2022 gives the warrant holder the right to subscribe for a new share at SEK 205.88 during May 2022.

If all warrants under the respective programs are converted to shares at the end of the period, the dilution effect for existing shares would be 2.5 percent as of 31 December 2020.

### Analysts

Pareto Securities and Danske Bank analyze XVIVO Perfusion regularly.

### OWNERSHIP STRUCTURE

According to Euroclear's official shareholder register, XVIVO Perfusion had 6,346 shareholders as of December 31, 2020. XVIVO Perfusion AB's (publ) ten largest shareholders as of December 31, 2020 are listed below.

Shareholder	Number of shares	Shares and votes, %
Bure AB Equity	4 322 504	15,1
Swedbank Robur	2 994 542	10,4
Fjärde AP-Fonden	1 875 000	6,5
Eccenovo AB	1 675 893	5,8
Handelsbanken Fonder	1 083 824	3,8
Lannebo Fonder	1 044 759	3,6
Miton Asset Management	1 011 340	3,5
Invesco	1 000 000	3,5
Tredje AP-fonden	520 000	1,8
Leif Bergwall	427 147	1,5
Övriga	12 764 127	44,5
<b>Total</b>	<b>28 719 136</b>	<b>100,0</b>

Source: Monitor's figures as of 31 December 2020.

### FINANCIAL REPORTS 2021

Interim Report January-March 2021:  
Wednesday, April 21, 2021  
Interim Report January-June 2021:  
Friday, July 13, 2021  
Interim Report January-September 2021:  
Thursday, October 28, 2021  
Year-End Report 2021:  
Thursday, January 27, 2022.

### INVESTOR RELATIONS

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# 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 2020 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. The company is active within all major organ areas and consists of two business areas: Thoracic (heart and lung) and Abdominal (liver and kidney).

XVIVO Perfusion employs around 80 people at its headquarters in Gothenburg, Sweden, its offices in Lund, Sweden, Groningen, Netherlands, and its office for North & South America in Denver, CO, USA. The XVIVO share is listed on NASDAQ Stockholm and is traded under the ticker symbol XVIVO. The total number of shares and votes are 28 719 136.

## Thoracic

Within the lung transplantation area, the company's product Perfadex® has a market share of approximately 90 percent in traditional static preservation of lungs prior to transplantation. A major problem in transplant care is the lack of available lungs. Today, scarcely 20 percent of available donation organs are used in the company's largest market, the United States, as it is deemed too risky to use the other donated lungs in transplantation. By using XVIVO Perfusion's product – STEEN Solution™ – the organ is cleared from harmful substances from the donor, creating a better environment for the organ's cells. The technology thereby allows the organ to "recover" when possible. It also allows for functional testing to be performed on the organ outside of the body. In clinical use in the US, Europe, Australia and Canada it has become apparent that once STEEN Solution™ perfusion has been carried out, many of the organs that were initially "rejected" are assessed as being usable and have been successfully transplanted into patients with end-stage lung disease. The use of STEEN Solution™ therefore has the potential to increase the total number of lung transplants. The company's products for warm perfusion, XPS™ and STEEN Solution™, have regulatory approval in all major markets in the world, and were the first products to receive regulatory approval from the FDA for warm perfusion of marginal lungs.

Based on the world leading research of Professor Stig Steen and his research group, XVIVO Perfusion's heart transplantation competence center in Lund (Sweden) has developed a machine and solutions for heart preservation. The products are developed to increase the availability of donated hearts so that more heart transplants can be performed, and more patients can be given a last chance of a longer life. Clinical multicenter trials are underway in Europe and in the USA and Australia trials are in the planning phase. The trials form the basis for applications for regulatory approvals for the products in all major markets.

## Abdominal

The shortage of transplantable kidneys is great. Studies have shown that transport of kidneys with ongoing perfusion in many cases improves post-transplant results. A high-quality international study has been published in The Lancet that shows significant benefits for the recipient when the kidney is transported in an oxygenated solution. This is the technology that is unique to XVIVO. XVIVO's technology, research and development in kidney perfusion is being used in both preclinical and clinical, investigator-driven studies.

Similarly to other organs, there is a shortage of transplantable livers. By preserving and evaluating the function of the donated liver in an optimized way, potentially more well-functioning organs could be transplanted. XVIVO's technology, research, and development in warm perfusion of the liver is being used in both preclinical and clinical, investigator-driven studies. The combination of new perfusion technology and XVIVO's solutions will be in focus for research and development within kidney and liver transplantation.

## Other indications

The company also invests in preclinical and clinical research in xenotransplantation, perfusion of organs remaining in the body, for example drug administration to isolated organs and priming solutions for heart-lung machines. An extended trial for the company's priming solution PrimeECC® is taking place in Sweden.

## Business concept

XVIVO Perfusion's business concept is to increase the survival rate of patients in need of an organ transplant by providing effective products that increase the availability of organs that have a good 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

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

## Strategy

XVIVO Perfusion's strategy is focused on increasing the number of organs available for transplantation. Through development of products for perfusion of organs and through clinical trials on all major markets in the world, XVIVO Perfusion shows that perfusion of organs gives more organs available for transplantation and thus gives a larger number of patients a life-saving treatment.

## Significant events

### **XVIVO completes the acquisition of the Dutch medical technology company Organ Assist B.V**

On September 23rd, XVIVO entered into an agreement to acquire 100 percent of the shares in the Dutch medical technology company Organ Assist B.V. Organ Assist focuses mainly on developing machines and consumables for perfusion of liver and kidney. Through the acquisition, XVIVO became the first company in the world who actively conducts business within preservation and evaluation of organs in all major organ areas. The acquisition accelerates the company's strategy to become a global supplier of solutions and systems in all major organ areas. The purchase price amounted to a maximum of EUR 24 million, with an initial payment of EUR 20 million and a conditioned, additional purchase price of maximum EUR 4 million. The additional payments are divided between two different payments of SEK 2 million each, where one is dependent on sales targets for 2021 and the other on regulatory FDA approval for the kidney transport device.

The acquisition of Organ Assist was financed through a directed share issue which took place in the same day as the acquisition. Investors included both existing and new shareholders, including Bure Equity AB, Swedbank Robur, Eccenovo AB (publ.), Fjärde AP-Fonden, Lannebo Fonder and Handelsbanken Fonder. The issue took place without discount at a subscription price of SEK 236 and the company raised approximately SEK 500 million. Issuance costs amounted to SEK 13.0 million. The number of shares and votes in XVIVO Perfusion AB (publ) was increased by 2,118,640 shares and amounts to 28,719,136.

### **Organizational changes**

Dag Andersson was appointed as the new President and CEO in April and took office in June. XVIVO Perfusion's founder and former CEO, Magnus Nilsson, remains as Senior Advisor to primarily work with R&D. Dag has a background in healthcare as CEO of Diaverum AB from 2008 up until 2018 and before that worked for 15 years in leading positions at the medical technology company Mölnlycke Health Care. A reorganization, which affected the company's management team and all departments, has taken place with the aim of creating a more efficient and focused organization. The management team has been strengthened with a new Commercial Director and a new R&D Director.

### **First patient in the European Heart Preservation study was transplanted**

The first patient in XVIVO's European Heart preservation study was transplanted during the month of November. The patent protected Heart Preservation device, developed by Professor Stig Steen and commercialized by XVIVO, uses a novel technique for preservation of the donor heart during transport. Nine European transplant centers will include a total of 202 patients in the trial that forms the basis of a European regulatory approval application and will investigate if the new technology can improve patient outcome and reduce complications after heart transplantation.

### **Heart preservation study from Lund published in Nature Communications**

During the period, the scientific journal Nature Communications published an article written by Professor Johan Nilsson, describing the use of XVIVO Perfusion's heart preservation technology developed by Professor Stig Steen. The results from the study show that our method is safe and functional for clinical use.

### **Publication in The Lancet shows better survival of transplanted kidneys after cold machine perfusion with oxygen**

In November, a study was published in the scientific journal The Lancet that shows that oxygenated perfusion of kidneys before transplantation has a significant impact on the first-year result after transplantation: less graft failure, better function and lower rejection of the kidney when compared to cold perfusion alone. The randomized trial, with kidneys from donors aged 50 years or older and donated after circulatory death, was performed in 19 European transplant centers and included 212 patients. The technology used in the study is CE-marked and XVIVO intends to submit an application during 2021 to the FDA, whose approval is required to enable a launch in the US market.

### **First patient in the extended PrimECC® study included**

PrimECC®, a CE-marked and patent-protected product, is developed to reduce complications after heart surgery. PrimECC® is a solution used to prime the heart-lung machine before open heart-surgery. Hundreds of thousands of heart surgeries are performed today each year worldwide using a heart-lung machine. The extended study that has now begun intends to expand and strengthen the clinical documentation for PrimECC® and will include a total of 366 patients.

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

	2020	2019	2018	2017	2016
Net sales, MSEK	180	221	188	148	138
Gross margin without capital goods, %	77	77	77	78	80
Gross margin, %	74	74	72	76	74
EBITDA, %*	-9	13	16	15	12
Operating margin %	-25	2	7	5	2
Net margin, %	-24	2	7	4	1
Total assets, MSEK	1 150	634	587	539	350
Equity/assets ratio, %	88	91	92	94	90
Earnings per share, SEK	-1,61	0,19	0,48	0,25	0,07
Equity per share, SEK	35,11	21,71	20,47	19,26	13,40
Share price at closing day, SEK	314	170	132	94	88
Antal anställda i medeltal	63	46	35	29	24

\*Operating profit before depreciation and amortization (EBITDA), adjusted for costs associated with organizational change, cost reservation for the share-based bonus programs for employees outside Sweden as well as integration and acquisition costs, amounts to SEK 20.2 million (35.8), corresponding to an EBITDA margin of 11 percent (16). Reported operating profit before depreciation and amortization (EBITDA) amounted to SEK -15.6 million (28.8), corresponding to an EBITDA margin of -9 percent (13).

### **Warrant program 2020/2022 final report**

The Annual General Meeting 2020 resolved to issue no more than of 408,000 warrants (series 2020/2022) with the accompanying right to subscribe for no more than 408,000 new shares for employees of the XVIVO Perfusion Group. Of these warrants, 374,000 have been subscribed for by employees. The warrant program 2020/2022 gives the warrant holder the right to subscribe for one new share at a price of SEK 205.88 in May 2022.

### **The Covid-19 pandemic**

In 2020, XVIVO has been affected by the ongoing Covid-19 pandemic through the reduction in transplants. Available healthcare resources have largely focused on Covid-19 patients and thus the number of donated organs has decreased and waiting lists have increased. During March to May, the decline was substantial. The important markets, the USA and Europe, gradually recovered during the third quarter.

### **Research and development**

XVIVO Perfusion mainly conducts product development on its own, while research is mainly carried out in collaboration with world-leading institutions and researchers in all major markets in the world. Considerable resources are spent on research and development and the company is one of the leading innovators in the industry. Of the total operating expenses of SEK 179 million (159), research and development costs accounted for SEK 56 million (63), corresponding to 31 (40) percent. During the year, development expenses of SEK 60 million (70) were capitalized as intangible assets.

Within lung transplantation, there is ongoing development together with our customers to ensure that our products are market leaders. During 2020, the company's focus has been on further developing machines and solutions to promote the use of EVLP.

Within heart transplantation the preservation machine with the solution and disposable kit, developed together with Professor Stig Steen, has now been used in clinical studies. First up was the European multicenter study, which was started in the fourth quarter of 2020. A similar multicenter study is in the planning phase in the US as well, where the company has received a so-called "breakthrough device designation" and the conditions for starting the study are under discussion with the FDA. In addition to the studies that XVIVO conducts, the Swedish investigator-driven study that uses XVIVO's technology continues to include patients. A supplementary investigator-driven study is also being launched in Australia. The Covid-19 pandemic have resulted in several hospitals putting their clinical studies on hold during the year.

In connection to the acquisition of Organ Assist, XVIVO Perfusion took over interesting development projects within kidney and liver transplants. The company's technical solutions within each organ area are CE-marked and thus approved for sale in Europe. Within the kidney area, the R&D during 2020 has focused on upgrading the unique technology of oxygenated perfusion of kidneys prior to FDA approval, as well as the global rollout to utilize the competitive advantages of the recently published article in the Lancet. Within the liver area, R&D has

focused on refining the technology prior to FDA approval, expanding clinical evidence through several European trials and investing in new protocols. During the year, XVIVO Perfusion continued to support clinical research on liver perfusion with STEEN Solution®. The combination of new perfusion technology and XVIVO's solutions will be in focus for future research within kidney transplants.

Beyond the R&D projects within the transplant area, the company also conducts a clinical study for the patented product PrimECC® - a priming solution which is being analysed in an extended study in several Swedish hospitals. The study included its first patient during the year.

Furthermore, the company supports research in a pre-clinical phase to potentially extend the use of warm perfusion with STEEN Solution™ for Xenotransplantation and administration of pharmaceuticals to isolated organs. In the longer term, it is interesting to treat isolated organs and tissues that remain in the body with adapted techniques, to avoid side effects in other parts of the body. An example of this is cancer treatment.

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

There are several 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 the company's ability to run or develop the business. XVIVO Perfusion's products need regulatory approval in the markets where they are marketed. The market for medical



device products is being regulated to a greater and greater extent with a view to increasing patient safety and reducing the risk of incorrect treatment. This means increased product development costs for XVIVO but also greater barriers for new competitors who want to break into the market. Due to the nature of the business, there is a risk of claims for damages and liability. 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).

### **Insurances**

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

### **Sustainability and responsibility**

The Board of Directors of XVIVO Perfusion has adopted a Code of Conduct which is anchored throughout the global organization. The Code of Conduct is based on the UN Declaration of Human Rights, the ILO Declaration on Fundamental Principles and Rights at Work, the UN Global Compact and the OECD Guidelines for Multinational Enterprises. The Code is reviewed and approved annually by the Board. The Code applies to all employees and sets the level of employee professionalism and integrity, with the aim of ensuring that each employee acts legally and appropriately in relation to the company's stakeholders.

The handling of personnel-related matters at XVIVO Perfusion is based on several policies and procedures. The most important ones are our Code of Conduct, work environment policy (including diversity and inclusion), health and safety practices and our privacy policy.

The high quality and safety of our products is crucial for our business. We constantly analyze and review the quality of the product's entire life cycle. Our quality management systems are certified according to standards applicable to the products we manufacture. XVIVO Perfusion follows the rules that apply where our products are being sold.

XVIVO Perfusion's business does not entail any specific environmental risks and does not require any special environmentally related permits or decisions from authorities. However, our business impacts the environment in several ways. Our customers are to be found all over the world, which means that our products are partly transported by air. The company strives to make its processes efficient in dialogue with customers and suppliers and tries to minimize the amount of transportation as far as possible. Global product ranges and extended shelf-life for products are examples of initiatives in recent years which reduce the company's impact on the environment. XVIVO Perfusion has employees in most continents and internal meetings are thus

held digitally to as great extent as possible and travel within the company only takes place when necessary. The company assesses that the business is run in accordance with the applicable health and safety rules and offers its employees a safe and healthy environment. Since transplantations are life-saving treatments, the products are governed by regulatory authorities.

### **Legal disputes**

The company was not involved in any legal disputes during 2020.

### **Outlook for 2021**

Sales development during 2021 will depend on the extent to which the Covid-19 pandemic affects intensive care in important markets. Transplantation is a life-sustaining treatment and transplants are prioritized by health authorities around the world. For this reason, the company estimates that the number of transplants, and thus the demand for XVIVO's products, will continue to increase long-term.

The company will intensify its efforts to receive regulatory approval of the Kidney Assist Transport device in the USA, which is the company's product for improved kidney transport. In 2020, very good study results were published in the Lancet which shows the benefits of XVIVO's technology, and the company aims to apply for 510K approval to the FDA in 2021. Costs for regulatory approval in the US will be capitalized on an on-going basis. The company will continue to focus heavily on clinical studies and product development in all major organ areas. In heart transplantation, the goal is to make great progress in the clinical multi centre studies in Europe, the USA and Australia. In kidney transplantation, the goal is to obtain regulatory approval in the USA for the kidney transport device during the second half of 2021. The PrimECC® study in Sweden should be able to pick up speed as the pressure on intensive care decreases.

### **The Board of Directors' proposal for guidelines for executive remuneration**

The executive management of XVIVO Perfusion AB (publ) ("XVIVO Perfusion") and the board of directors, insofar as remuneration other than that decided by the general meeting is paid to board members, fall within the provisions of these guidelines. The executive management includes the CEO, the deputy CEO and other members of the executive management. Other members of the executive management refer to senior managers and those who report directly to the CEO. Managers who report directly to the CEO are in the company's case CFO, COO, CCO, CMO, Global QA&RA Director and Global Research and Development Director.

The guidelines are forward-looking, i.e. they are applicable to remuneration agreed, and amendments to remuneration already agreed, after adoption of the guidelines by the annual general meeting 2021. These guidelines do not apply to any remuneration decided or approved by the general meeting.

For employments governed by rules other than Swedish, pension benefits and other benefits may be duly adjusted for compliance with mandatory rules or established local practice, considering, to the extent possible, the overall purpose of these guidelines.

***The guidelines' promotion of the company's business strategy, long-term interests and sustainability***

XVIVO Perfusion is a medical device company that develops and markets solutions and systems for assessing usability, enabling treatment of organs and preserving organs in good condition outside the body while waiting for a transplantation. The company is active within all of the major organ areas; heart, lung, liver and kidney.

The company is currently the market leader within lung transplantation and provides transplant clinics all over the world with high-tech products for storing and evaluating lungs. XVIVO Perfusion has around 80 employees that work at its head office in Gothenburg, offices in Lund, Groningen in the Netherlands and at the office for North and South America in Denver, USA. For further information about the company's business strategy, see [www.xvivoperfusion.com](http://www.xvivoperfusion.com).

Successful implementation of the company's business strategy and taking care of the company's long-term interests, including its sustainability, presuppose that the company can recruit, motivate and retain skilled employees through competitive remuneration that is in line with market rates. These guidelines enable senior executives to be offered a competitive total remuneration. The company has established two long-term share-related incentive programs. They have been resolved by the General Meeting and are therefore not covered by these guidelines. For the same reason, the long-term share-related incentive program proposed by the Board for the 2021 Annual General Meeting is also not covered. The proposed program essentially corresponds to existing programs, but the number of participants has been limited. The programs include key employees in the Group as well as senior executives in the company. The programs have a clear connection to the business strategy and thus to the company's long-term value creation, including its sustainability. The programs also impose requirements regarding longer period of holding. For more information about these programs, see [www.xvivoperfusion.com](http://www.xvivoperfusion.com).

***Types of remuneration, etc.***

The remuneration shall be on market terms and may consist of the following components: fixed cash salary, variable cash remuneration, pension benefits and other benefits. Additionally, the general meeting may – irrespective of these guidelines – resolve on, among other things, share-related or share price-related remuneration. The fixed cash salary shall be determined with consideration of the concerned individual's responsibilities and experience. The fixed salary shall be reviewed annually. The satisfaction of criteria for awarding variable cash remuneration shall be possible to measure over a period of one year. The variable cash remuneration may amount to not more than 50 percent of the fixed annual cash salary for the CEO and 30 percent of the fixed annual cash salary for other members of the executive management.

Additional variable remuneration may be awarded in extraordinary circumstances, provided that such extraordinary arrangements are limited in time and only made on an individual basis, either for the purpose of recruiting or retaining executives, or as remuneration for extraordinary performance beyond the individual's ordinary tasks. Such remuneration may not exceed

an amount corresponding to 30 percent of the fixed annual cash salary and may not be paid more than once each year per individual. Any resolution on such remuneration shall be made by the board of directors based on a proposal from the remuneration committee.

***Pension***

For the CEO of the company, pension benefits, including health insurance (Sw: sjukförsäkring), shall be premium defined. Variable cash remuneration shall not qualify for pension benefits. The pension premiums for premium defined pension shall amount to not more than 35 percent of the fixed annual cash salary. For other executives, pension benefits, including health insurance, shall be premium defined unless the individual concerned is subject to defined benefit pension under mandatory collective agreement provisions. Variable cash remuneration shall not qualify for pension benefits. The pension premiums for premium defined pension shall amount to not more than 31,5 percent of the fixed annual cash salary.

Other benefits may include, for example, life insurance, medical insurance (Sw: sjukvårdsförsäkring) and company cars. Such benefits shall be determined on the criteria of marketability and competitiveness.

For executives stationed in another country than their home country, additional remuneration and other benefits may be awarded to a reasonable extent with consideration of the special circumstances that are associated with such foreign stay, whereby the general purpose of these guidelines shall be satisfied to the furthest extent possible.

***Termination of employment***

The notice period may not exceed six months if notice of termination of employment is made by the company. If notice of termination of employment is made by the company, severance pay corresponding to no more than the same amount as twelve monthly salaries shall be awarded to the CEO. No severance pay shall be awarded to other members of the executive management upon termination of their employment. The period of notice may not exceed six months when termination is made by the executive, without any right to severance pay.

Additionally, remuneration may be paid for non-compete undertakings. Such remuneration shall compensate for loss of income and shall only be paid insofar as the previously employed executive is not entitled to severance pay. The remuneration shall be based on the fixed cash salary at the time of termination of employment and be paid during the time that the non-compete undertaking applies, which shall be not more than 12 months following termination of employment.

***Criteria for awarding variable cash remuneration, etc.***

The variable cash remuneration shall be linked to predetermined and measurable criteria which can be financial or non-financial and be individualized quantitative or qualitative targets. The criteria shall be designed to contribute to the company's business strategy and long-term interests, including its sustainability, by for example being clearly linked to the business strategy or promote the executive's long-term development.

To which extent the criteria for awarding variable cash remuneration has been satisfied shall be evaluated/determined when the measurement period has ended. The remuneration committee is responsible for the evaluation so far as it concerns variable remuneration to the CEO. For variable cash remuneration to other executives, the CEO is responsible for the evaluation. For financial objectives, the evaluation shall be based on the latest financial information made public by the company.

### **Salary and employment conditions for employees**

In the preparation of the board of directors' proposal for these remuneration guidelines, salary and employment conditions for employees of the company have been taken into account by including information on the employees' total remuneration, the components of the remuneration and increase and growth rate of the remuneration over time, in the remuneration committee's and the board of directors' basis of decision when evaluating whether the guidelines and the limitations set out herein are reasonable. The development of the gap between the remuneration to executives and remuneration to other employees will be disclosed in the remuneration report.

### **The decision-making process to determine, review and implement the guidelines**

The board of directors has established a remuneration committee. The committee's tasks include preparing the board of directors' decision to propose guidelines for executive remuneration. The board of directors shall prepare a proposal for new guidelines at least every fourth year and submit it to the annual general meeting. The guidelines shall be in force until new guidelines are adopted by the general meeting. The remuneration committee shall also monitor and evaluate programs for variable remuneration for the executive management, the application of the guidelines for executive remuneration as well as the current remuneration structures and compensation levels in the company. The ordinary members of the remuneration committee are independent of the company and its executive management. The CEO and other members of the executive management do not participate in the board of directors' processing of and resolutions regarding remuneration-related matters in so far as they are affected by such matters.

### **Board of directors' service assignments**

Directors elected by the general meeting shall in special cases be eligible for remuneration for services within their respective area of competence, which is not board work. Remuneration for such services shall be made on market terms and approved by the board of directors and may not exceed SEK 300,000 excluding VAT per year and director.

### **Derogation from the guidelines**

The board of directors may resolve to temporarily derogate from the guidelines, in whole or in part, if in a specific case there is special cause for such action and a derogation is necessary to serve the company's long-term interests, including its sustainability, or to ensure the company's financial viability. As set out above, the remuneration committee's tasks include preparing the board of directors' resolutions in remuneration-related matters, which includes resolutions to derogate from the guidelines.

### **Description of significant changes to the guidelines and how the views of shareholders' have been taken into consideration**

The proposal for guidelines submitted at the 2021 annual general meeting includes several clarifications, in accordance with applicable law. However, the proposal does not include any significant changes in relation to the company's current guidelines for remuneration. XVIVO Perfusion has not received any views from shareholders to take into consideration in the preparation of this proposal.

### **Parent Company**

The business focuses on sales of lung transplant products outside of North America, global research and development and global marketing. During the year SEK 57 million (75) was invested in the business, of which SEK 56 million (71) was invested in intangible assets.

### **Proposal for profit appropriation**

The following equity is at the disposal of the Annual General Meeting:

Share premium reserve	992 291 064 SEK
Retained earnings	-151 942 686 SEK
Net income for the year	-38 436 084 SEK
	801 912 294 SEK

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

To be carried forward	801 912 294 SEK
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The financial reports were approved for issuance by the Board of the Parent Company on March 29, 2021.

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 realize 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 Perfusion 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 cash-based incentive programs for participants in countries where allocation of warrants is not appropriate. The time period of the two 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 2020 Annual Report in note 24. Further information on corporate governance in XVIVO Perfusion is to be found at [www.xvivoperfusion.com](http://www.xvivoperfusion.com).

## Ownership

According to Monitor's shareholder register, XVIVO Perfusion had 6,346 shareholders as of December 31, 2020, an increase of 16% compared to the previous year. XVIVO Perfusion AB's (publ) ten largest shareholders as of December 31, 2020 are listed below:

Shareholder	Number of shares	Shares and votes, %
Bure Equity AB	4 322 504	15,1
Swedbank Robur	2 994 542	10,4
Fjärde AP-Fonden	1 875 000	6,5
Eccenovo AB	1 675 893	5,8
Handelsbanken Fonder	1 083 824	3,8
Lannebo Fonder	1 044 759	3,6
Miton Asset Management	1 011 340	3,5
Invesco	1 000 000	3,5
Tredje AP-fonden	520 000	1,8
Leif Bergwall	427 147	1,5
Övriga	12 955 009	44,4
Total	28 719 136	100,0

Source: Monitor's compilation on 31 December 2020.

## Shares

As of December 31, 2020, the share capital of XVIVO Perfusion AB (publ) was SEK 734,025 allocated among 28,719,136 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.

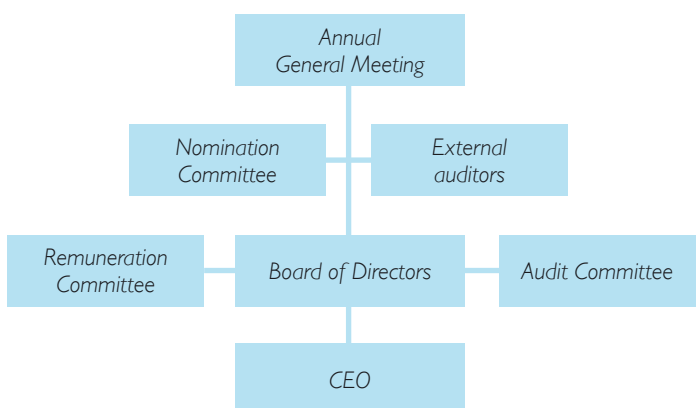
At the XVIVO Perfusion Annual General Meeting on Mars 31, 2020, it was resolved that for the period until the next Annual General Meeting and on one or more occasions, the Board of Directors is authorized to issue a maximum of 2,660,000 shares, corresponding to 10 % of the total number of shares and votes in the company.

A resolution was adopted at XVIVO Perfusion's Annual General Meeting held on Mars 31, 2020 to issue no more than 408,000 warrants entitling warrant holders to subscribe for new shares. The warrants were offered to all employees in the two Swedish group companies. Of these warrants, a total of 374,000 has been subscribed by employees. If these warrants are fully utilized, the share capital will increase by SEK 9,724, corresponding to a dilution of approximately 1.3 percent of the total number of shares and votes in the company.

A directed rights issue was carried out during the third quarter of 2020. The company received SEK 500,000,000 in connection with the share issue. The share capital increased by SEK 54,150 and the excess part, SEK 499,945,850, was recognized as share premium. The issue expenses were 12,954,550 SEK.

## 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 in and vote at the meeting. Shareholders who are unable to attend may be represented by a proxy.

## Annual General Meeting 2020

The last Annual General Meeting was held on March 31, 2020 in Gothenburg. At the Meeting it was decided to re-elect the board members Gösta Johannesson, Camilla Öberg, Folke Nilsson, Yvonne Mårtensson and Dag Andersson. Gösta Johannesson was elected Chairman of the Board. A resolution was passed to adopt board fees of a total of SEK 1,005,000 SEK, of which SEK

250,000 to the Chairman, SEK 150,000 to each of the other board members and SEK 40,000 to the Chairman of the Audit Committee, SEK 40,000 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 2019 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 2,660,000 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 408,000 warrants entitling warrant holders to subscribe for new shares was approved.

### **Extraordinary General Meeting 2020**

An Extraordinary General Meeting was held on 14 October 2020. The Annual General Meeting decided that the Board of Directors shall consist of six members until the next Annual General Meeting. The Meeting elected Lena Höglund and Lars Henriksson as board members. Dag Andersson resigned from the board, due to his appointment as CEO of the company as of June 1, 2020. It was decided that board fees should be adjusted to a total of SEK 1,092,500.

### **Annual General Meeting 2021**

The Annual General Meeting will be held on Thursday, April 22, 2021 at 3:00 p.m. at the Svenska Mässan, visiting address: Mässans gata 24, in Gothenburg. Advance voting by postal voting will be allowed in accordance with information in the notice. Shareholders who wish to participate in the Annual General Meeting shall be registered in the share register kept by Euroclear Sweden AB no later than Wednesday, April 14, 2021. Shareholders who wish to attend the Annual General Meeting shall notify the Company no later than April 16, 2021. Either by writing to XVIVO Perfusion AB (publ), the Annual General Meeting 2021, c/o Advokatfirman Vinge KB, Box 110 25, 404 21 Gothenburg, by e-mail to [xvivoperfusion@vinge.se](mailto:xvivoperfusion@vinge.se), or by sending their postal vote in accordance with the instructions in the notice.

## **The Board**

### **General**

The Board is responsible for the company's administration of its affairs and organization. At the Annual General Meeting held in Mars 2020, five Board members were elected, and at the Extraordinary General Meeting in October 2020 six 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 served as the Board's secretary. In 2020, the Board held 17 meetings (11), 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	17/17	3/3	
Folke Nilsson		17/17		5/5
Camilla Öberg		17/17		5/5
Yvonne Mårtensson		17/17	2/2	3/3
Alan Raffensperger		3/3		2/2
Dag Andersson		15/15	1/1	
Lena Höglund		2/2	1/1	
Lars Henriksson		2/2	1/1	

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

The CEO has participated at all the Board meetings. Other senior executives have attended dependent on the addressed issues. Remuneration and other benefits paid to the Board of XVIVO Perfusion are detailed in Note 7 of the 2020 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.

2020 was a special year in the wake of the Covid-19 pandemic, since all individuals and organizations had to take a great responsibility in order to limit the spread of infection. For this reason, the Board of Directors changed its way of working during the year. Physical board meetings have been kept to a minimum in favor of digital meetings. Travel within the board assignment has also been reduced. During the year, focus has been on the effects of the pandemic on XVIVO's operations. In early spring 2020, the company developed and expanded its forecasting to be able to quickly address the effects of the pandemic on sales and studies, which resulted in a cost-cutting program. During the year, the Board of Directors followed and assessed sales and cost forecasts carefully.

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 Mars 31, 2020. 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. At the autumn of 2019, the Board evaluated its work by doing 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 board members also weighted the importance of each statement for the boards work and the company's long-term value growth. The responses were compiled by independent third parties and compared with the benchmark index of listed companies in the Nordic region. The evaluation is a part of constantly developing the board work and the next evaluation will take place in autumn 2021.

### **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 2020 Annual Report, page 72, and the company's website ([www.xvivoperfusion.com](http://www.xvivoperfusion.com)).

### **Remuneration Committee**

At the inaugural Board meeting, the Board of XVIVO Perfusion appoints 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 instructions. The Group's guidelines for remuneration of executive management are included in the Administration Report on pages 46-47 of the 2020 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), Lars Henriksson and Lena Höglund.

### **Audit Committee**

At the inaugural Board meeting, the Board of Directors of XVIVO Perfusion appoints an audit committee. The tasks of the Audit Committee are described in an instruction for the Audit Committee. The purpose of the Audit Committee's activities is to assist the Board of Directors of XVIVO Perfusion in questions regarding financial reporting, auditing and risk management. The Audit Committee is a preparatory body and the Board has overriding responsibility for the questions related to auditing. The members of the Audit Committee shall consist of at least three board members appointed by the Board at the inaugural Board meeting or whenever otherwise necessary. The members of the Committee may not be employed by the Company. At least one member shall be independent in relation to the company's major

shareholders and should have accounting or audit experience. The Audit Committee consists of Camilla Öberg (Chairman of the Audit Committee), Yvonne Mårtensson 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 73 of the 2020 Annual Report and the company's website ([www.xvivoperfusion.com](http://www.xvivoperfusion.com)). XVIVO Perfusion's management team consists of seven members, CEO included. The management team has competence and experience from research and development, quality assurance, regulatory affairs, quality assurance, marketing, production and distribution of medical device equipment. Furthermore, the members of the management team have the necessary competence in economics and finance. The management team meets every other week. Two times a year the team meets for all-day meetings, which provides the opportunity to deal with issues of a more strategic nature. The instruction for the Board of Directors and the CEO was determined on the statutory Board meeting on Mars 31, 2020 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**

At the Annual General Meeting 2020, KPMG AB was appointed as the company's audit firm. During the year, KPMG AB have appointed authorized public accountant Daniel Haglund as auditor in charge up until the end of 2021 Annual General Meeting. Daniel Haglund has reported his observations from the audit to the 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 2021 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 2021 – shall contact the three largest shareholders of XVIVO Perfusion AB (publ) on the basis of known shareholdings at the end of August 2020 and ask them to appoint one member each to be included in the Nomination Committee. In addition to these three members, the Chairman of the Board shall also be part of 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 2020 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 five 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 in the event of 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 and 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 logbook 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

1 JANUARY – 31 DECEMBER

SEK thousands

	Note	2020	2019
Net sales	2	179 861	220 837
Cost of goods sold		-46 886	-58 024
<b>Gross income</b>	3	<b>132 975</b>	<b>162 813</b>
Selling expenses		-59 899	-60 786
Administrative expenses		-30 342	-24 739
Research and development costs		-56 178	-62 651
Other operating revenues	5	1 468	1 738
Other operating expenses	6	-33 699	-12 435
<b>Operating income</b>	7, 8, 9, 10, 12	<b>-45 675</b>	<b>3 940</b>
Financial income		890	1 690
Financial expenses		-12 478	-340
<b>Net financial income</b>	11, 12	<b>-11 588</b>	<b>1 350</b>
<b>Income before taxes</b>		<b>-57 263</b>	<b>5 290</b>
Tax on income for the year	14	13 528	-351
<b>Net income for the year</b>		<b>-43 735</b>	<b>4 939</b>
<b>Net income for the year attributable to:</b>			
Parent Company shareholders		-43 735	4 939
Basic earnings per share, SEK		-1,61	0,19
Diluted earnings per share, SEK*		-1,60	0,18
Average number of outstanding shares before dilution		27 171 352	26 518 546
Average number of outstanding shares after dilution*		27 354 518	26 799 996
Number of shares at closing day before dilution		28 719 136	26 600 496
Number of shares at closing day after dilution*		29 444 136	26 879 496

\* After dilution. See Note 24 for information about warrant programs.

# CONSOLIDATED STATEMENT OF TOTAL COMPREHENSIVE INCOME

1 JANUARY – 31 DECEMBER

SEK thousands

	Note	2020	2019
<b>Net income for the year</b>		<b>-43 735</b>	<b>4 939</b>
<b>Other comprehensive income</b>			
<i>Items that have been or may be reclassified to the income statement</i>			
Exchange-rate differences		-16 410	3 721
Tax attributable to items that have been or may be transferred to the income statement	14	0	-514
<b>Total other comprehensive income for the year, net after tax</b>	23	<b>-16 410</b>	<b>3 207</b>
<b>Total comprehensive income for the year</b>		<b>-60 145</b>	<b>8 146</b>
<b>Total comprehensive income for the year attributable to:</b>			
Parent Company shareholders		-60 145	8 146

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

SEK thousands	Note	2020-12-31	2019-12-31
<b>ASSETS</b>	27,28		
<b>Non-current assets</b>			
INTANGIBLE ASSETS	15		
Capitalized development expenditure		393 969	266 517
Patents, licenses and trademarks		5 467	5 382
Goodwill		223 938	65 773
Computer programs		1 283	837
TANGIBLE ASSETS	16		
Machinery, equipment, fixtures and fittings		21 334	23 554
FINANCIAL ASSETS			
Deferred tax asset	14	40 334	12 316
Other financial assets		754	223
<b>Total non-current assets</b>		<b>687 079</b>	<b>374 602</b>
<b>Current assets</b>			
INVENTORIES	18	59 351	43 871
CURRENT RECEIVABLES			
Accounts receivable - trade	20	40 183	43 725
Tax assets		156	491
Other receivables		3 361	4 894
Prepaid expenses and accrued income	21	5 943	6 958
CASH AND CASH EQUIVALENTS	22	354 236	159 946
<b>Total current assets</b>		<b>463 230</b>	<b>259 885</b>
<b>TOTAL ASSETS</b>		<b>1 150 309</b>	<b>634 487</b>
SEK thousands	Note	2020-12-31	2019-12-31
<b>SHAREHOLDERS' EQUITY</b>	23,24		
<b>Shareholders' equity attributable to Parent Company shareholders</b>			
Share capital		734	680
Other capital contributed		1 006 784	515 753
Reserves		-182	16 228
Retained earnings incl. net income for the year		1 125	44 860
<b>TOTAL SHAREHOLDERS' EQUITY</b>		<b>1 008 461</b>	<b>577 521</b>
<b>LIABILITIES</b>			
Other provisions		1 311	1 314
Deferred tax liability	14	24 853	899
Other long-term liabilities	27	40 150	-
Interest-bearing liabilities, non-current	10	3 286	2 154
<b>Total long-term liabilities</b>	27,28,29	<b>69 600</b>	<b>4 367</b>
Interest-bearing liabilities, current	10	3 926	3 396
Accounts payable		14 468	14 406
Current tax liability		-	-
Other liabilities		1 239	1 765
Accrued expenses and deferred income	26	52 615	33 032
<b>Total current liabilities</b>	27,28,29	<b>72 248</b>	<b>52 599</b>
<b>TOTAL LIABILITIES</b>		<b>141 848</b>	<b>56 966</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>		<b>1 150 309</b>	<b>634 487</b>



# CONSOLIDATED CHANGES IN SHAREHOLDERS' EQUITY

SEK thousands	Attributable to Parent Company shareholders				Total shareholder's equity
	Share capital	Other capital contributed	Reserves	Retained earnings incl. net income for the year	
<b>Opening shareholders' equity at 2019-01-01</b>	<b>675</b>	<b>486 860</b>	<b>13 021</b>	<b>39 921</b>	<b>540 477</b>
COMPREHENSIVE INCOME FOR THE YEAR					
Net income for the year	-	-	-	4 939	4 939
Other comprehensive income for the year	-	-	3 207	-	3 207
Total comprehensive income for the year	-	-	3 207	4 939	8 146
TRANSACTIONS WITH GROUP'S SHAREHOLDERS					
<i>Contributions from and value transfers to shareholders</i>					
New share issue minus transaction expenses, net after tax*	5	27 296	-	-	27 301
Premium paid upon issue of warrants	-	1 597	-	-	1 597
Total contributions from and value transfers to shareholders	5	28 893	-	-	28 898
<b>Closing shareholders' equity at 2019-12-31</b>	<b>680</b>	<b>515 753</b>	<b>16 228</b>	<b>44 860</b>	<b>577 521</b>
COMPREHENSIVE INCOME FOR THE YEAR					
Net income for the year	-	-	-	-43 735	-43 735
Other comprehensive income for the year	-	-	-16 410	-	-16 410
Total comprehensive income for the year	-	-	-16 410	-43 735	-60 145
TRANSACTIONS WITH GROUP'S SHAREHOLDERS					
<i>Contributions from and value transfers to shareholders</i>					
New share issue minus transaction expenses, net after tax*	54	489 640	-	-	489 694
Premium paid upon issue of warrants	-	1 391	-	-	1 391
Total contributions from and value transfers to shareholders	54	491 031	-	-	491 085
<b>Closing shareholders' equity at 2020-12-31</b>	<b>734</b>	<b>1 006 784</b>	<b>-182</b>	<b>1 125</b>	<b>1 008 461</b>

\* Transaction costs in connection with new share issue amount to SEK 10 286 thousand (84).

# CONSOLIDATED CASH FLOW STATEMENT

1 JANUARY – 31 DECEMBER

SEK thousands

	Note	2020	2019
<b>Operating activities</b>	31		
Income after financial items		-57 263	5 290
Adjustment for non-cash items		49 355	28 862
Taxes paid		142	-2 945
		<b>-7 766</b>	<b>31 207</b>
Increase (-)/Decrease (+) in inventories		-14 155	-8 478
Increase (-)/Decrease (+) in operating receivables		20 584	-542
Increase (-)/Decrease (-) in operating liabilities		-10 929	7 318
<b>Cash flow from operating activities</b>		<b>-12 266</b>	<b>29 505</b>
<b>Investing activities</b>			
Acquisition of intangible fixed assets		-62 046	-73 190
Acquisition of property, plant and equipment		-2 631	-10 503
Divestment of property, plant and equipment		-	-
Acquisition of subsidiaries		-201 319	-
Acquisition of other financial assets		-536	-151
<b>Cash flow from investing activities</b>		<b>-266 532</b>	<b>-83 844</b>
<b>Financing activities</b>			
Warrants program		1 391	1 475
New share issue		487 044	27 425
Part-payment of lease liability		-5 667	-3 349
<b>Cash flow from financing activities</b>		<b>482 768</b>	<b>25 551</b>
<b>Cash flow for the year</b>		<b>203 970</b>	<b>-28 788</b>
Cash and cash equivalents at beginning of year		159 946	187 064
Exchange-rate difference in cash and cash equivalents		-9 680	1 669
<b>Exchange-rate difference in cash and cash equivalents</b>	22	<b>354 236</b>	<b>159 946</b>

# INCOME STATEMENT FOR THE PARENT COMPANY

1 JANUARY – 31 DECEMBER

SEK thousands

	Note	2020	2019
Net sales	2	134 122	169 608
Cost of goods sold		-36 107	-50 677
<b>Gross income</b>		<b>98 015</b>	<b>118 931</b>
Selling expenses		-36 675	-35 842
Administrative expenses		-27 602	-18 485
Research and development costs		-65 268	-65 937
Other operating revenues	5	1 269	4 034
Other operating expenses	6	-11 343	-4 875
<b>Operating income</b>	7, 8, 9, 10, 12	<b>-41 604</b>	<b>-2 174</b>
<b>PROFIT/LOSS FROM FINANCIAL ITEMS</b>			
Interest income and similar items		1 581	5 838
Interest expenses and similar items		-12 190	-1 064
<b>Income after financial items</b>	11, 12	<b>-52 213</b>	<b>2 600</b>
Appropriations	13	4 200	-2 300
Tax on income for the year	14	9577	-299
<b>Net income for the year</b>		<b>-38 436</b>	<b>1</b>

The Parent Company has no items to be recognized in other comprehensive income and therefore no statement of total comprehensive income has been presented.

# BALANCE SHEET FOR THE PARENT COMPANY

SEK thousands	Note	2020-12-31	2019-12-31
<b>ASSETS</b>	27, 28		
<b>Non-current assets</b>			
INTANGIBLE ASSETS	15		
Capitalized development expenditure		239 509	200 672
Patents, licenses and trademarks		4 985	4 696
Computer programs		1 283	837
PROPERTY, PLANT AND EQUIPMENT	16		
Machinery, equipment, fixtures and fittings		5 902	7 924
FINANCIAL ASSETS			
Participating interests in Group companies	4, 17	404 467	161 174
Receivables from Group companies	19	34 550	25 771
Deferred tax liability	14	13 921	1 677
Other financial assets		660	125
<b>Total non-current assets</b>		<b>705 277</b>	<b>402 876</b>
<b>Current assets</b>			
INVENTORIES	18	16 561	15 070
CURRENT RECEIVABLES			
Accounts receivable - trade	20	17 987	22 216
Receivables to Group companies		56	224
Current tax assets		1	1 275
Other receivables		2 904	5 266
Prepaid expenses and accrued income	21	4 654	5 371
CASH AND BANK BALANCES	22	333 318	150 362
<b>Total current assets</b>		<b>375 481</b>	<b>199 784</b>
<b>TOTAL ASSETS</b>		<b>1 080 758</b>	<b>602 660</b>
SEK thousands	Note	2020-12-31	2019-12-31
<b>SHAREHOLDERS' EQUITY</b>	23, 24		
RESTRICTED EQUITY			
Share capital		734	680
Statutory reserve		20	20
Reserve for development costs		198 151	148 855
NON-RESTRICTED EQUITY	30		
Share premium reserve		992 291	501 242
Balanserat resultat		-151 943	-102 648
Net income for the year		-38 436	1
<b>TOTAL SHAREHOLDERS' EQUITY</b>		<b>1 000 817</b>	<b>548 150</b>
<b>Untaxed reserves</b>	25	<b>-</b>	<b>4 200</b>
<b>PROVISIONS</b>			
Other provisions		1 311	1 315
<b>Total provisions</b>		<b>1 311</b>	<b>1 315</b>
<b>NON-CURRENT LIABILITIES</b>			
Other liabilities		40 150	11 552
<b>Total non-current liabilities</b>	22	<b>40 150</b>	<b>48 995</b>
<b>CURRENT LIABILITIES</b>	22		
Accounts payable		8 349	11 552
Liabilities to Group companies	19	3 574	19 002
Current tax liability		-	-
Other liabilities		1 133	654
Accrued expenses and deferred income	26	25 424	17 787
<b>Total current liabilities</b>	27, 28, 29	<b>38 480</b>	<b>48 995</b>
<b>TOTAL LIABILITIES</b>		<b>79 941</b>	<b>54 510</b>
<b>TOTAL SHAREHOLDER'S EQUITY AND LIABILITIES</b>		<b>1 080 758</b>	<b>602 660</b>



# CHANGES IN SHAREHOLDERS' EQUITY FOR THE PARENT COMPANY

SEK thousands	Restricted shareholders' equity			Non-restricted shareholders' equity			Total share- holder's equity
	Share capital	Statutory reserve	Development expenditure fund	Share premium reserve	Retained earnings	Net income for the year	
<b>Opening shareholders' equity at 2019-01-01</b>	<b>675</b>	<b>20</b>	<b>84 348</b>	<b>472 345</b>	<b>-45 939</b>	<b>7 798</b>	<b>519 247</b>
Net income for the year	-	-	-	-	-	1	1
Other comprehensive income for the year	-	-	-	-	-	-	-
Total comprehensive income for the year	-	-	-	-	-	1	1
Proposed appropriation of profits	-	-	-	-	7 798	-7 798	0
New share issue minus transaction expenses, net after tax*	5	-	-	27 336	-	-	27 341
Premium paid upon issue of warrants	-	-	-	1 561	-	-	1 561
Allocation to reserve for development expenditure	-	-	64 507	-	-64 507	-	0
<b>Closing shareholders' equity at 2019-12-31</b>	<b>680</b>	<b>20</b>	<b>148 855</b>	<b>501 242</b>	<b>-102 648</b>	<b>1</b>	<b>548 150</b>
Net income for the year	-	-	-	-	-	-38 436	-38 436
Other comprehensive income for the year	-	-	-	-	-	-	0
Total comprehensive income for the year	-	-	-	-	-	-38 436	-38 436
Proposed appropriation of profits	-	-	-	-	1	-1	0
New share issue minus transaction expenses, net after tax*	54	-	-	489 659	-	-	489 713
Premium paid upon issue of warrants	-	-	-	1 390	-	-	1 390
Allocation to reserve for development expenditure	-	-	49 296	-	-49 296	-	0
<b>Closing shareholders' equity at 2020-12-31</b>	<b>734</b>	<b>20</b>	<b>198 151</b>	<b>992 291</b>	<b>-151 943</b>	<b>-38 436</b>	<b>1 000 817</b>

\*Transaction costs in connection with new share issue amounted to SEK 10 286 thousand (84).

# CASH FLOW STATEMENT FOR THE PARENT COMPANY

1 JANUARY – 31 DECEMBER

SEK thousands	Note	2020	2019
<b>Operating activities</b>	31		
Income after financial items		-52 213	2 600
Adjustment for non-cash items		35 211	17 524
Taxes paid		1 276	-2 199
		<b>-15 726</b>	<b>17 925</b>
Increase (-)/Decrease (+) in inventories		-7 321	-2 554
Increase (-)/Decrease (+) in operating receivables		-1 735	-5 563
Increase (-)/Decrease (-) in operating liabilities		-13 525	-4 355
<b>Cash flow from operating activities</b>		<b>-38 307</b>	<b>5 453</b>
<b>Investing activities</b>			
Investments in intangible fixed assets		-55 848	-71 379
Acquisition of property, plant and equipment		-1 611	-4 053
Change in loan to Group company		-	11 804
Acquisition of group companies		-201 320	-
Acquisition of other financial assets		-	-54
<b>Cash flow from investing activities</b>		<b>-258 779</b>	<b>-63 682</b>
<b>Financing activities</b>			
Warrants program		1 391	1 599
New share issue, net after transaction expenses		487 044	27 301
<b>Cash flow from financing activities</b>		<b>488 435</b>	<b>28 900</b>
<b>Cash flow for the year</b>		<b>191 349</b>	<b>-29 329</b>
Cash and cash equivalents at beginning of year		150 362	178 248
Exchange-rate difference in cash and cash equivalents		-8 393	1 443
<b>Cash and cash equivalents at end of year</b>	22	<b>333 318</b>	<b>150 362</b>

# SUPPLEMENTARY DISCLOSURES AND NOTES TO THE FINANCIAL REPORTS

Notes to the financial statements for the full year 2020 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 Mässans gata 10, postal address Box 53015, SE-400 14 Gothenburg. 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 RFR 1 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, except for additional purchase price related to business acquisitions, which is measured at fair value.

### 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 34.

### CLASSIFICATION

Non-current assets, long-term liabilities and provisions essentially consist only of amounts that are expected to be recovered or paid more than 12 months after closing day. Current assets and current liabilities essentially consist only 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), the wholly-owned French subsidiary XVIVO Perfusion SAS, the Australian subsidiary XVIVO Perfusion Pacific Pty Ltd and the Dutch subsidiary Organ Assist B.V with subsidiaries, which were acquired in 2020.

#### 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 other subsidiaries 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	
	2020	2019	2020-12-31	2019-12-31
USD	9,2037	9,4604	8,1886	9,3172
EUR	10,4867	10,5892	10,0375	10,4336
AUD	6,3380	6,5724	6,2646	6,5125

Source: Sweden's Riksbank

### REVENUE

The group's net sales are divided into three categories: sales of non-durable goods, revenues from sales and rental of durable goods and finally revenues from freight, service and other sales (see note 2). Sale of non-durable goods and revenues from freight, service and other sales comprise products and services that clearly represent separate performance obligations. 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 normally occurs upon delivery.

### 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 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.

### LEASING

#### LESSEE

In accordance with IFRS 16, right-of-use such as rental agreements for premises and equipment is recognized as an asset in the balance sheet and a lease liability is recognized, which represents an obligation to make future lease payments related to the right-of-use. An exemption has been utilized, whereby short-term leases and lease contracts of low value are not recognized as an asset but are expensed in the period when use occurs. The company defines short-term leases as contracts whose remaining lease term is less than 12 months and by contracts of low value is meant contracts whose cost is less than SEK 50 thousand. The Parent Company does not apply IFRS 16, in accordance with the exception in RFR 2.

## LESSOR

At December 31, 2020 XVIVO Perfusion had entered into 3 (4) leases with customers regarding XPS machines and 1 (1) lease regarding LS machines. Due to the fact that XVIVO Perfusion is liable for all risk regarding the machines' residual value and service needs, the assessment has been made that by and large all financial risks and benefits associated with the machines relate to XVIVO Perfusion. Based on these qualitative factors, the conclusion is drawn that the leases are operating leases. Lease payments pursuant to operating lease contracts, including an initial higher rent payment but excluding expenses for services that are insurance and maintenance, are recognized as revenue on a straight-line basis over the term of the lease.

## FINANCIAL INSTRUMENTS

IFRS 9 Financial instruments is applied by the Group. 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.

Regarding impairment of financial assets, the company uses a model based on expected future credit losses, the "expected credit loss model". The impairment model is applied to financial assets measured at amortized cost or at fair value via other comprehensive income, except for investments in equity instruments (shares and participations) and contract assets. There were not any significant credit losses during the year and the Group's provisions for future credit losses at closing day do not amount to a significant amount either.

In connection to business acquisitions, additional purchase price is valued at fair value with changes in value in the income statement.

## 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, trademarks and computer programs.

## CAPITALIZED DEVELOPMENT EXPENDITURE

Research costs are expenditure for research with the aim of gaining new scientific or technical knowledge. Development expenditure is 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, but only if 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
Licenses and trademarks	10 years
Computer programs	5 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 at 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. The value in use is 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 7.

## 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 24.

## 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 are stated below. 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.

## LEASED ASSETS

In the Parent Company, all leases are classified as operating leases when the Parent Company is the lessee. Lease payments pursuant to operating lease contracts, including an initial higher rent payment but excluding expenses for services that are insurance and maintenance, are recognized as an expense on a straight line basis over the term of the lease.

## NOTE 2. NET SALES

### DISTRIBUTION OF NET SALES

	Group		Parent Company	
	2020	2019	2020	2019
Sales of non-durable goods	161 762	198 271	126 516	159 292
Revenues from sales and rental of durable goods	10 436	13 981	5 511	6 227
Revenues from freight, service and other sales	7 663	8 586	2 095	4 090
Total	179 861	220 837	134 122	169 608

The Group had no customer during 2020 and 2019 that constituted more than 10% of total sales.

Of the Group's and the Parent Company's total revenues, SEK 1,866 thousand (2,208 thousand) relates to operating lease income (see Note 10 Leases).

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

## GEOGRAPHICAL AREAS

	Group			
	Revenues from external customers		Non-current assets	
	2020	2019	2020	2019
Sweden	1 306	1 165	608 096	353 269
Americas	108 132	137 603	6 076	8 795
EMEA excluding Sweden	60 989	65 097	31 819	-
Asia/Pacific	9 434	16 972	-	-
Total	179 861	220 837	645 991	362 063

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 rental revenues from machines.
- All non-durable goods: revenue flows from sales of goods and services that are not durable goods.

### GROUP SEGMENTS - TOTAL

	All business except durable goods		Durable goods		Consolidated total	
	2020	2019	2020	2019	2020	2019
Revenues from external customers	169 425	206 857	10 436	13 981	179 861	220 837
Cost of goods sold	-38 980	-47 439	-7 906	-10 585	-46 886	-58 024
Gross income	130 445	159 417	2 530	3 396	132 975	162 813

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.

Since 2020, the company's operations have been conducted in two business areas; Thoracic, which includes sales of lung and heart transplant products, as well as Abdominal, which includes sales of liver and kidney transplant products. The Group's operating segments can be found in each business area.

### GROUP SEGMENTS – PER BUSINESS AREA – THORACIC

	All business except durable goods		Durable goods		Consolidated total	
	2020	2019	2020	2019	2020	2019
Revenues from external customers	155 572	206 857	7 720	13 981	163 292	220 837
Cost of goods sold	-32 048	-47 439	-6 291	-10 585	-38 339	-58 024
Gross income	123 524	159 417	1 429	3 396	124 953	162 813

### GROUP SEGMENTS – PER BUSINESS AREA - ABDOMINAL

	All business except durable goods		Durable goods		Consolidated total	
	2020	2019	2020	2019	2020	2019
Revenues from external customers	13 853	-	2 716	-	16 569	-
Cost of goods sold	-6 932	-	-1 615	-	-8 547	-
Gross income	6 921	-	1 101	-	8 022	-

## NOTE 4 ACQUISITION OF SUBSIDIARIES

On September 1, XVIVO entered into an agreement to acquire 100 percent of the shares in the Dutch medical technology company Organ Assist B.V. The purchase price amounted to a maximum of EUR 24 million, with an initial payment of EUR 20 million and a conditioned, additional purchase price of maximum EUR 4 million. The additional payments are divided between two different payments of SEK 2 million each, where one is dependent on sales targets for 2021 and the other on regulatory FDA approval for the kidney transport device. The acquisition of Organ Assist was successfully financed through a directed share issue in which SEK 500 million were raised through a directed share issue.

Costs related to the acquisition have so far amounted to SEK 2.7 million and have been charged to administrative expenses in the Group's income statement during the year. Transaction costs directly attributable to the share issue have been recognized as equity and amount to SEK 10.3 million net after tax.

Organ Assist focuses mainly on developing machines and consumables for perfusion of the liver and kidneys. Through the acquisition, XVIVO will be the first company for the preservation and evaluation of organs in the world to actively conduct activities that include all major organs, which accelerates the company's strategy to become a global supplier of solutions and systems for all major organs. The companies' synergies enable greater market opportunities for XVIVO's and Organ Assist's product portfolios by integrating XVIVO's unique and patented STEEN Solution™ technology with Organ Assist's kidney and liver devices, as well as by utilizing XVIVO's international market presence. The combined offering expands XVIVO's addressable market to approximately 98 percent of the organ transplant market with the goal of positioning the company as the first choice for all multi-organ clinics.

Goodwill primarily consists of synergy effects that do not meet the requirements for accounting as intangible assets at the time of the acquisition. Primary synergies are potentially increased sales values per client as well as increased sales potential for new clients, which can be achieved through XVIVOS knowledge and experience within global marketing and regulatory issues. Synergies which could contribute to future net sales is also to be found within research and development.

The acquisition date is October 1 and income and cash flow are not included in the consolidated financial statements until this date. During the time after the acquisition, Organ Assist contributed with SEK 16.6 million to the net sales of the group and SEK 1.1 million to the net result. If the acquisition had taken place on January 1st 2020, the entity would have contributed with net sales of SEK 41.8 million and a net result of -3.1 million.

Transferred compensation	Fair value (TSEK)
Cash and cash equivalents	201 320
Conditional purchase price	41 973
Total	243 293

### Acquired net assets

Intangible assets	87 372
Property, plant and equipment	1 475
Inventories	14 360
Accounts receivable and other receivables	18 155
Cash and cash equivalents	1
Deferred tax liability	-12 706
Accounts payable and other liabilities	-31 257
Fair value of acquired net assets	77 400

Goodwill	165 893
Total	243 293

### Effect on cash flow from acquisition of business

Purchase price, initial cash part	201 320
Less cash and cash equivalents in acquired company	1
Impact on the Group's cash and cash equivalents	201 319

## NOTE 5. OTHER OPERATING REVENUES

	Group		Parent Company	
	2020	2019	2020	2019
Exchange-rate gains	936	1 369	904	1 354
Other Revenues	532	369	365	2 680
Total	1 468	1 738	1 269	4 034

## NOTE 6. OTHER OPERATING EXPENSES

	Group		Parent Company	
	2020	2019	2020	2019
Exchange-rate losses	-2 425	-1 342	-2 123	-1 260
Other Intra-Group services	-	-	-	-128
Cost of share-based bonus program*	-18 260	-7 046	-3 342	-660
Cost of reorganization	-9 873	-	-3 584	-
Capital loss, sale of non-current asset	-	-58	-	-
Depreciation of durable goods	-3 141	-3 989	-2 294	-2 827
Total	-33 699	-12 435	-11 343	-4 875

\*See notes 5 and 7 for information.

## NOTE 7. EMPLOYEES, EMPLOYEE BENEFIT EXPENSES AND BOARD FEES

### AVERAGE NUMBER OF EMPLOYEES

	Total		Number of men	
	2020	2019	2020	2019
Parent Company, Sweden	28	18	12	7
Subsidiary, Sweden	10	10	8	8
Subsidiary, USA	19	16	13	10
Subsidiary, Netherlands	4	-	3	-
Subsidiary, France	1	1	-	-
Subsidiary, Australia	1	1	1	1
Total	63	46	37	26

### PERCENTAGE OF WOMEN IN SENIOR POSITIONS

	2020	2019
<b>Group</b>		
Board	50 %	33 %
Senior management	29 %	17 %

### EMPLOYEE BENEFIT EXPENSES

<b>Group</b>	2020	2019
Salary and other remuneration	75 793	51 131
Pension expenses, defined contribution plans	7 789	6 293
Social security contributions	16 566	13 359
Total	100 148	70 783
<b>Parent Company</b>	2020	2019
Salary and other remuneration	34 598	23 025
Pension expenses, defined contribution plans	6 247	4 199
Social security contributions	11 832	7 908
Total	52 677	35 132

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

	Board/CEO		Other employees	
	2020	2019	2020	2019
Parent Company	4 392	8 784	31 214	15 467
- of which bonus payments and similar remuneration	(-)	(2 219)	(2 140)	(1 358)
Subsidiaries	-14	2 341	41 209	25 765
- of which bonus payments and similar remuneration	(-14)	(719)	(22 500)	(10 267)
Total	4 378	11 125	72 423	41 232
- of which bonus payments and similar remuneration	(-14)	(2 938)	(24 640)	(11 625)

### BOARD

Board fees of SEK 1 180 thousand (1 035) were paid during the year, in accordance with the resolution adopted at the 2019 Annual General Meeting. SEK 250 thousand (205) was paid to Gösta Johannesson and SEK 150 thousand (130) 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. There are no pension expenses or pension obligations for the Board members.

At the Annual General Meeting held on April 31, 2020 in Gothenburg a resolution was adopted that Board fees will remain unchanged on individual level totaling SEK 1 180 thousand (1 180) until the next Annual General Meeting. SEK 250 thousand (250) will be paid to Chairman of the Board and SEK 150 thousand (150) 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

During the past year of 2020, XVIVO Perfusion AB has had two CEOs, since Dag Andersson succeeded Magnus Nilsson on June 1 2020. During the year, CEO Magnus Nilsson was paid remuneration totaling SEK 1 620 (9 173) thousand including vacation allowance and other benefits of which SEK- thousand (2 219) was variable remuneration. A car allowance and health-insurance benefit of SEK 58 thousand (84) was paid. During 2020, CEO Dag Andersson was paid remuneration totaling SEK 1 862 (-) thousand including vacation allowance and other benefits of which SEK - thousand (-) was variable remuneration. A car allowance and health-insurance benefit of SEK 54 thousand (-) was paid.

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. 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 10 463 thousand (10 057) was paid during the 2020 financial year to senior executives, the Group's management team of 6 (5) people excluding the CEO, including a vacation allowance, of which SEK 4 485 thousand (3 134) 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 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.

	Group		Parent Company	
	2020	2019	2020	2019
Costs for defined contribution pension plans	7 789	6 293	6 247	4 199

### 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. During 2020 and 2019 nothing was paid for this endowment insurance.

### COSTS FOR SHARE-BASED WARRANTS PROGRAM FOR EMPLOYEES ABROAD

The 2019 and 2020 Annual General Meetings adopted a resolution to approve a cash-based incentives program for Group employees in countries outside of Sweden as these employees are not entitled to participate in the Swedish warrants programs. The cash-based programs shall as far as practically possible be designed so that they correspond to the Swedish warrants programs but have a ceiling for maximum outcome. The cost of these cash-based incentive programs is recognized in the periods XVIVO's share price is higher than the strike price for each Swedish warrants program. The Group's cost amounted to SEK 18 260 (7 046) (see notes 6 and 24) and is included in the item bonus payments/variable remuneration above. In the functionally divided income statement, this expense is recognized as other operating expenses.

### GOVERNMENT SUPPORT

Government support has been received in the USA and Australia of SEK 4.2 million, which has been reported as reduced personnel cost, mainly within the sales and R&D functions. In Sweden, government support has been received through reduced employer contribution fees. No layoffs or furlough has occurred. Information on labor costs listed in this note is reported before deduction of contributions received.

## NOTE 8. AUDITOR'S FEES AND REIMBURSEMENT OF COSTS

	Group		Parent Company	
	2020	2019	2020	2019
<b>KPMG</b>				
Auditing	650	420	250	250
Auditing activities in addition to auditing	31	5	31	5
Tax consulting	297	8	254	8
Other services	96	67	96	67
Total	1 074	500	631	330

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 9. OPERATING EXPENSES DIVIDED UP ACCORDING TO TYPE OF COST

	Group	
	2020	2019
Raw materials and consumables	-25 897	-28 850
Change in inventories of finished goods and products in progress	-8 169	-22 563
Employee benefit expenses	-103 726	-88 012
Depreciation, amortization and impairment	-30 038	-24 860
Other external expenses	-56 911	-52 950
Other operating expenses	-2 263	-1 400
Total	-227 004	-218 635

## NOTE 10. 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, 2021 with an option for extension. The Group also rents office premises and warehouse facilities in Denver, Colorado. The current rental agreement expires on August 1, 2022 with an option for extension. The Group also rents office premises and warehouse facilities in Lund. This rental agreement expires on October 31, 2022 with an option for extension. The Group also rents office premises and warehouse facilities in Groningen, Netherlands. This rental agreement expires on December 1, 2021 with an option for extension.

Rental payments are linked to CPI and vary with the market as a whole. Variable payments are invoiced 1:1 in arrears after an annual review. There are no restrictions as a result of lease 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. Otherwise, the Group has entered into lease agreements for three company cars and some office equipment.

	Group	
	2020	2019
Cost disclosures, leases:		
Depreciation of right-of-use assets	5 667	3 349
- Of which buildings	5 361	3 166
- Of which cars	306	183
Interest expense, lease liability	222	161
Lease expense for short-term leases	130	142
Lease expense for assets of low value	-	-
Variable lease expenses	282	150
Total	6 301	3 802

	Group	
	2020	2019
Cash flow disclosures, leases		
Part-payment of lease liability	5 667	3 349
Interest expense, lease liability	222	161
Lease expense for short-term leases	130	142
Lease expense for assets of low value	-	-
Variable lease expenses	282	150
Total	6 301	3 802

	Group	
	2020	2019
Additional right-of use assets		
Buildings	6 869	-
Cars	500	425
Total	7 329	425

	Group	
	2020	2019
Carrying amount of right-of-use assets		
Byggnader	6 550	5 082
Bilar	662	468
Total	7 212	5 550

	Group	
	2020	2019
Carrying amount of lease liabilities		
Lease liabilities	7 212	5 550
Total	7 212	5 550

A lease analysis for agreed minimum future lease payments payable pursuant to non-reversible contracts is presented in note 27.

Payments expensed for operating leases are as follows:

	Group	
	2020	2019
Minimum lease payments	2 214	1 907
Total lease expenses	2 214	1 907

The Group rents out machines for lung perfusion pursuant to operating leases. Revenues amounted to SEK 1 866 thousand (2 208). Future non-reversible lease payments fall due as follows:

	Group		Parent Company	
	2020	2019	2020	2019
Year 1	1 022	2 208	1 022	2 208
Year 2	-	944	-	944
Year 3	-	-	-	-
Year 4	-	-	-	-
Year 5	-	-	-	-
Later than 5 years	-	-	-	-
Total	1 022	3 152	1 022	3 152

## NOTE 11. NET FINANCIAL INCOME

	Group		Parent Company	
	2020	2019	2020	2019
Interest income	80	469	725	1 358
Exchange-rate gains	810	1 230	856	4 480
Financial income	890	1 699	1 581	5 838
Interest expenses	-361	-285	-129	-120
Exchange-rate losses	-11 916	-	-11 890	-900
Other financial expenses	-201	-64	-171	-44
Financial expenses	-12 478	-349	-12 190	-1 064
Total	-11 588	1 350	-10 609	4 774

## NOTE 12. EXCHANGE-RATE DIFFERENCES

	Group		Parent Company	
	2020	2019	2020	2019
In operating income, net	-1 333	27	-1 219	94
In financial items, net	-11 106	1 230	-11 034	3 580
Total	-12 439	1 257	-12 253	3 674

## NOTE 13. YEAR-END ADJUSTMENTS

	Parent Company	
	2020	2019
Change in tax allocation reserve	4 200	5 950
Group contributions paid	-	-8 250
Total	4 200	-2 300

## NOTE 14. INCOME TAXES

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

	Group		Parent Company	
	2020	2019	2020	2019
<b>Current tax expense (-)</b>				
Tax expense for the year	-782	-1 212	-	-574
Adjustment of tax pertaining to previous years	561	759	2	-
Total current tax expense	-221	-453	2	-574
<b>Deferred tax expense (-)</b>				
Deferred tax on temporary differences	1 475	109	480	275
Deferred tax in taxable value capitalized/utilized during the year in loss carry-forwards	12 680	-7	9 448	-
Effects from changed income tax rates	-406	-	-352	-
Total deferred tax expense	13 749	102	9 575	275
Total tax expense recognized	13 528	-351	9 577	-299

	Group		Parent Company	
	2020	2019	2020	2019
<b>Reconciliation effective tax rate</b>				
Income before tax	-57 263	5 290	-48 013	301
Tax pursuant to current tax rate for Parent Company (21.4 %)	12 254	-1 132	10 275	-64
Difference in foreign tax rates	-59	17	-	-
Non-deductible expenses	-1 120	-126	-343	-189
Non-taxable income	2 303	180	1	3
Tax effect of standard interest rate on tax allocation reserve	-4	-49	-4	-49
Effect of changed income tax rates	-406	-	-352	-
Difference in recorded and paid tax previous year	561	759	2	-
Total tax expense	13 528	-351	9 577	-299

#### Tax attributable to other comprehensive income

	Group			Parent Company		
	2020		2019		2019	
	Before tax	After tax	Before tax	After tax	Before tax	After tax
Translation differences for the year after translation of foreign businesses	-8 674	-	-8 674	1 319	-	1 319
Translation differences for the year after translation of foreign businesses (extended investment)	-7 736	-	-7 736	2 402	-514	1 888
Other comprehensive income	-16 410	-	-16 410	3 721	-514	3 207

#### RECOGNIZED DIRECTLY IN SHAREHOLDERS' EQUITY

	Group		Parent Company	
	2020	2019	2020	2019
<b>Tax items recognized directly in shareholders' equity</b>				
<b>Tax expense (-)</b>				
Current tax related to transaction expenses for new share issue	-2 669	-	-2 669	-
Total tax items recognized directly in shareholders' equity	-2 669	-	-2 669	-

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

	Group		Parent Company	
	2020	2019	2020	2019
<b>Deferred tax asset</b>				
Deferred tax related to internal profit on inventories	2 972	2 875	-	-
Deferred tax related to pensions and similar obligations	2 157	1 677	2 157	1 677
Deferred tax related to capitalized loss carry-forwards	35 205	7 764	11 764	-
Total deferred tax asset	40 334	12 316	13 921	1 677
<b>Deferred tax liability</b>				
Deferred tax on tax allocation reserve	-	899	-	-
Deferred tax on acquired excess value	24 852	-	-	-
Total deferred tax liability	24 852	899	-	-

## NOTE 15. INTANGIBLE NON-CURRENT ASSETS

	Group		Parent Company	
	2020	2019	2020	2019
<b>Goodwill</b>				
Opening acquisition cost	65 773	65 614	-	-
Acquired assets for the year	165 893	-	-	-
Exchange-rate differences for the year	-7 728	159	-	-
Closing accumulated acquisition cost	223 938	65 773	-	-
Closing carrying amount	223 938	65 773	-	-

	Group		Parent Company	
	2020	2019	2020	2019
<b>Capitalized development expenditure</b>				
Opening acquisition cost	336 141	266 390	258 167	190 227
Capitalized expenditure for the year	60 497	69 751	54 299	67 940
Acquired assets for the year	87 372	-	-	-
Exchange-rate differences for the year	-3 791	-	-	-
Closing accumulated acquisition cost	480 209	336 141	312 466	258 167
Opening amortization	-69 624	-55 930	-57 495	-43 800
Amortization for the year	-16 668	-13 694	-15 462	-13 695
Exchange-rate differences for the year	52	-	-	-
Closing accumulated amortization	-86 240	-69 624	-72 957	-57 495
Closing carrying amount	393 969	266 517	239 509	200 672

#### Patents, licenses and trademarks

Opening acquisition cost	10 038	7 482	7 302	4 745
Capitalized expenditure for the year	990	2 556	990	2 557
Closing accumulated acquisition cost	11 028	10 038	8 292	7 302
Closing accumulated acquisition cost	-4 656	-3 858	-2 606	-2 019
Amortization for the year	-905	-798	-701	-587
Closing accumulated amortization	-5 561	-4 656	-3 307	-2 606
Closing carrying amount	5 467	5 382	4 985	4 696

#### Data programs

Opening acquisition cost	882	-	882	-
Capitalized expenditure for the year	559	882	559	882
Closing accumulated acquisition cost	1 441	882	1 441	882
Closing accumulated acquisition cost	-46	-	-46	-
Amortization for the year	-113	-46	-113	-46
Closing accumulated amortization	-159	-46	-159	-46
Closing carrying amount	1 283	837	1 283	837

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

	Group		Parent Company	
	2020	2019	2020	2019
Cost of goods sold	-	-	-	-
Selling expenses	-	-	-	-
Administrative expenses	-113	-46	-113	-46
Research and development costs	-17 572	-14 493	-16 162	-14 280
Other operating expenses	-	-	-	-
Total	-17 685	-14 539	-16 275	-14 326

The Group's goodwill is attributable to acquisitions of subsidiaries and their businesses. Goodwill primarily consists of synergy effects that do not meet the requirements for accounting as intangible assets at the time of the acquisition. Primary synergies are potentially increased sales values per client as well as increased sales potential for new clients, which can be achieved through XVIVOS knowledge and experience within global marketing and regulatory issues. Synergies which could contribute to future net sales is also to be found within research and development. 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.

The forecast cash flows have been calculated with a discount rate of 8.9 per cent before tax for assets in the lung business, and 9.6-11.4 per cent before tax for assets in the abdominal business. The main variables in the forecast are market share and growth, gross margin, sales costs and investments. The calculation is based on continued good gross margin and the investment need to replace existing assets has been deemed to be relatively low. The labour capital has been assumed to change in proportion to turnover and the debt/equity ratio is expected to remain unchanged as growth has been assumed to take place within the framework of the existing operations and with own resources. The recoverable amount, which is calculated in the Group as value in use, exceeds the carrying amount. Management believes that no reasonable changes in the important variables and assumptions result in the entity'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 16. PROPERTY, PLANT AND EQUIPMENT

	Group		Parent Company	
	2020	2019	2020	2019
<b>Machinery, equipment, fixtures and fittings</b>				
Opening acquisition cost	49 753	32 872	20 213	16 160
Adjustment for changed accounting principle*	-	8 712	-	-
Acquisitions for the year	9 944	10 690	1 611	4 053
Acquired assets for the year	1 480			
Sales/disposals for the year	-628	-1 581	-1	-
Exchange-rate differences for the year	-1 777	-940	-	-
Closing accumulated acquisition cost	58 772	49 753	21 823	20 213
Opening depreciation	-26 199	-17 257	-12 290	-8 793
Sales/disposals for the year	179	158	1	-
Depreciation for the year	-12 343	-10 321	-3 632	-3 497
Exchange-rate differences for the year	925	1 221	-	-
Closing accumulated depreciation	-37 438	-26 199	-15 921	-12 290
Closing carrying amount	21 334	23 554	5 902	7 924

\* Adjustment for changed accounting principle refers to introduction of IFRS 16 Leases.

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

	Group		Parent Company	
	2020	2019	2020	2019
Cost of goods sold	-462	-815	-	-
Selling expenses	-2 148	-1 215	-	-
Administrative expenses	-3 041	-2 170	-1 338	-670
Research and development costs	-3 561	-2 132	-	-
Other operating expenses	-3 141	-3 989	-2 294	-2 827
Total	-12 353	-10 321	-3 632	-3 497

## NOTE 17. PARTICIPATIONS IN GROUP COMPANIES

	Parent Company	
	2020	2019
Opening acquisition cost	161 174	161 174
Acquisitions for the year	243 293	-
Closing carrying amount	404 467	161 174

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

Book value						
Company	Corp.Reg.No.	Domicile	No. of shares	Participation in %	2020	2019
XVIVO Perfusion Inc.	45-5472070	Denver, USA	1 000	100	14 475	14 475
XVIVO Perfusion Lund AB	556761-1701	Lund, Sverige	11 402 818	100	146 651	146 651
XVIVO Perfusion SAS	531 229 219	Lyon, Frankrike	5 000	100	48	48
XVIVO Perfusion Pacific Pty Ltd	637303381	Melbourne, Australien	1	100	-	-
Organ Assist B.V.	02082540	Groningen, Netherlands	1 035 170	100	243 293	-
- Organ Assist Products B.V.	01135421	Groningen, Netherlands	18 000	100	-	-
Total					404 467	161 174

## NOTE 18. INVENTORIES

	Group		Parent Company	
	2020	2019	2020	2019
Raw materials and consumables	17 311	21 131	3 558	8 670
Work in progress	3 055	2 899	1 647	-
Finished goods and goods for resale	38 985	19 841	11 356	6 400
Total	59 351	43 871	16 561	15 070

The Group's closing inventories include impairment of SEK 8 879 thousand (3 016) for obsolescence of inventories. In the Parent Company there is impairment of SEK 7 010 thousand (TSEK 1 179).

## NOTE 19. RECEIVABLES FROM AND LIABILITIES TO GROUP COMPANIES

The Parent Company has net receivables from the subsidiary XVIVO Perfusion Inc. in the amount of SEK 14 375 thousand (25 750) and receivables on Organ Assist B.V. of SEK 20 175 thousand (-), liabilities to the subsidiary XVIVO Perfusion Lund AB in the amount of SEK 2 276 thousand (17 379), liabilities to the subsidiary XVIVO Perfusion Pacific Pty Ltd of SEK 218 thousand (-) and net liabilities to the subsidiary XVIVO Perfusion SAS in the amount of SEK 1 024 thousand (1 399)

## NOTE 20. 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 2020 amounted to SEK 340 thousand (-), of which SEK 226 thousand (-) was in the Parent Company. Bad debt losses in the Group for which provisions were made during the year amount to SEK 298 thousand (272), of which SEK 298 thousand (82) was in the Parent Company.

	Group		Parent Company	
	2020	2019	2020	2019
Accounts receivable - trade	40 563	43 997	18 367	22 298
Minus provisions for doubtful receivables	-380	-272	-380	-82
Total	40 183	43 725	17 987	22 216

### Age structure – trade accounts receivable

Not due	22 749	27 866	6 476	13 160
Due 0-30 days ago	4 079	8 082	1 967	2 091
Due 31-90 days ago	7 123	5 390	4 574	4 428
Due 91-180 days ago	1 004	1 476	601	1 454
Due > 180 days ago	5 607	1 183	4 749	1 165
Total	40 563	43 997	18 367	22 298

## NOTE 21. PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent Company	
	2020	2019	2020	2019
Rent and other property costs	460	467	361	369
Prepaid insurance	2 953	2 860	2 491	2 370
Other prepaid expenses	2 530	3 631	1 802	2 632
Total	5 943	6 958	4 654	5 371

## NOTE 22. 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	
	2020	2019	2020	2019
Cash and bank balances	354 236	159 946	333 318	150 362
Total	354 236	159 946	333 318	150 362

There were no short-term investments.

Cash and cash equivalents include bank balances frozen as security for bank guarantees of SEK 0.8 million (0.8) 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 (30) in the Parent Company.

## NOTE 23. SHAREHOLDERS' EQUITY

### SHARE CAPITAL

There is only one class of shares and all shares carry the same rights. At December 31, 2020 the registered share capital comprised 28,719,136 shares (26,600,496).

### 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	
	2020	2019
Opening value	16 228	13 021
Exchange-rate difference for the year in foreign subsidiaries, net after tax	-16 410	3 207
Total	-182	16 228

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, which 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 24. 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	2020	2019
Consolidated net income for the year	-43 735	4 939
Weighted average number of shares before dilution	27 171 352	26 518 546
Dilution effect of warrants program	183 167	281 450
Weighted average number of shares after dilution	27 354 518	26 799 996
Earnings per share before dilution, SEK	-1,61	0,19
Earnings per share after dilution, SEK	-1,60	0,18

### WARRANTS PROGRAM

In total there are 725,000 outstanding warrants in two programs.

The 2019 Annual General Meeting resolved to issue no more than 351,000 warrants (series 2019/2021), entitling employees of the XVIVO Perfusion Group to subscribe for no more than 351,000 new shares. All these 351,000 warrants have been subscribed for by employees. Warrants program 2019/2021 entitles warrant holders to subscribe for new shares in May 2021 at a price of SEK 278.91.

The 2020 Annual General Meeting resolved to issue no more than 408,000 warrants (series 2020/2022), entitling employees of the XVIVO Perfusion Group to subscribe for no more than 408,000 new shares. Of these warrants, 374,000 have been subscribed for by employees. Warrants program 2020/2022 entitles warrant holders to subscribe for new shares in May 2022 at a price of SEK 205.88.

During the period January-December 2020, both the average share price for the period and the closing share price per December 31 exceeded the strike price of warrant program series 2019/2021. Upon maturity, the warrants program is estimated to entail a total dilution effect for existing shares of approximately 2.58 %.

The 2019 and 2020 Annual General Meetings adopted a resolution to approve a cash-based incentive program for Group employees in countries outside of Sweden as these employees are not entitled to participate in the Swedish warrants programs. The cash-based programs shall as far as practically possible be designed so that they correspond to the Swedish warrants programs but have a ceiling for maximum outcome. The cost of these cash-based incentive programs is recognized in the periods XVIVO's share price is higher than the strike price for each Swedish warrants program. The cost is accounted for under "other operating expenses" and is described in note 6.

## NOTE 25. UNTAXED RESERVES

	Parent Company	
	2020	2019
Tax allocation reserves		
Allocation, assessment of tax 2017	-	700
Allocation, assessment of tax 2018	-	3 500
Total	-	4 200

## NOTE 26. ACCRUED EXPENSES AND DEFERRED INCOME

	Group		Parent Company	
	2020	2019	2020	2019
Vacation pay	8 034	5 977	5 788	4 259
Accrued social security contributions	4 317	2 705	2 607	1 812
Accrued special employer's contribution for pension expenses	2 530	1 751	1 903	1 274
Accrued salary, pension and bonus	26 587	11 140	10 359	6 144
Board fees	1 378	1 551	1 378	1 551
Auditing	285	290	210	250
Other accrued expenses	5 769	7 840	2 703	2 247
Deferred income	3 715	1 778	476	250
Total	52 615	33 032	25 424	17 787

## 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 and interest rates, refinancing risks 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.



## LEASE ANALYSIS

Maturity structure of financial liabilities:

	Within 1 year	2 years	3 years	4 years	5 years	>5 years	Total
2019-12-31							
Interest-bearing liabilities (leases)	3 396	1 127	142	-	-	-	5 550
Accounts payable	14 406	-	-	-	-	-	14 406
Other liabilities	34 797	-	-	-	-	-	34 797

2020-12-31							
Interest-bearing liabilities (leases)	3 926	2 356	930	-	-	-	7 212
Other long-term liabilities (non interest-bearing)	-	40 150					40 150
Accounts payable	14 468	-	-	-	-	-	14 468
Other liabilities	53 854	-	-	-	-	-	53 854

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

## CREDIT RISKS

The Group's financial assets are recognized at SEK 404 million (354), of which SEK 354 million (160) is cash and cash equivalents. Historically, the Group has had low credit losses and this was also true for 2020. 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 during 2020 was primarily in EUR, 81 percent (85). 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. In the other subsidiaries intra-Group revenues in local currency are matched with costs, which are essentially in the same local currency.

## 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 2 million (4) for the year that ended on December 31, 2020.

## NOTE 28. FAIR VALUE AND CARRYING AMOUNTS OF FINANCIAL ASSETS AND LIABILITIES

### GROUP

Financial assets and liabilities amounted to SEK 240 million (216) and SEK 76 million (55), respectively. There has been no forward cover for the currency components included in the above figures.

### PARENT COMPANY

Financial assets and liabilities amounted to SEK 359 million (185) and SEK 38 million (49), 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	
	2020	2019	2020	2019
<b>Assets in balance sheet</b>				
Loans and receivables	40 183	43 725	17 987	22 216
Other current receivables	9 460	12 343	7 615	12 136
Cash and cash equivalents	354 236	159 946	333 318	150 362
Total	403 879	216 014	358 920	184 714

### Financial liabilities measured at amortized cost

	Group		Parent Company	
	2020	2019	2020	2019
<b>Liabilities in balance sheet</b>				
Interest-bearing liabilities (leases)	7 212	5 550	-	-
Accounts payable	14 468	14 406	8 349	11 552
Other liabilities	53 854	34 797	30 131	37 443
Total	75 534	54 753	38 480	48 995

### Financial liabilities measured at fair value

	Group		Parent Company	
	2020	2019	2020	2019
<b>Liabilities in balance sheet</b>				
Other liabilities	40 150	-	40 150	-
Total	40 150	-	40 150	-

The Group's assets and liabilities in the balance sheet are measured at amortized cost except for liabilities for additional purchase price related to acquisition of businesses, which is measured at fair value. 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 29. PLEDGED ASSETS FOR OWN LIABILITIES

	Group		Parent Company	
	2020	2019	2020	2019
Chattel mortgages	30 000	30 000	27 000	27 000
Bank guarantees	750	770	750	770
Total	30 750	30 770	27 750	27 770

## NOTE 30. APPROPRIATION OF NON-RESTRICTED EQUITY

### PROPOSED ALLOCATION OF NON-RESTRICTED EQUITY

Share premium reserve	992 291 064
Retained earnings	-151 942 686
Net income for the year	-38 436 084
Earnings at the disposal of the AGM	801 912 294
To be carried forward	801 912 294 kr

## NOTE 31. CASH FLOW STATEMENT

	Group		Parent Company	
	2020	2019	2020	2019
<b>Interest received</b>				
Interest paid	80	469	725	1 358
Total	-361	-281	-129	-120
Summa	-281	188	596	1 238

### Adjustment for non-cash items

Depreciation, amortization and impairment of assets	30 038	24 860	19 907	17 823
Provisions for doubtful trade accounts receivable	380	272	380	83
Inventory obsolescence	6 641	2 678	5 830	1 179
Capital gain from sales of fixed assets	391	1 440	-	-
Changes in provisions	-4	-14	-4	-14
Translation differences/exchange-rate differences	11 909	-374	9 098	-1 547
Total	49 355	28 862	35 211	17 524

## NOTE 32. TRANSACTIONS WITH RELATED PARTIES

### RELATED PARTIES

The Parent Company is closely associated with the subsidiaries. Of the Parent Company's total revenues and purchases, SEK 70,329 thousand (83,427) are revenues from the subsidiaries and SEK 50,060 thousand (80,245) 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 2019 and 2020, except in one case: The Board member Folke Nilsson invoiced the company SEK 69 thousand (93) in 2020 for consultancy services in the field of heart transplantation. Total remuneration paid is presented in the note "Employees, employee benefit expenses and Board fees" (see note 7).

## 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.

During 2020, XVIVO has been affected by the ongoing Covid-19 pandemic by a decrease in the number of transplants. The impact on sales in 2021 will depend on the extent to which the pandemic will affect intensive care in the US and Europe. Transplantation is a life support treatment and transplants are prioritized by health authorities around the world. The company therefore estimates that the number of transplants, and thus the demand for XVIVO Perfusion products, will continue to increase in the long term.

## NOTE 34. CRITICAL ASSESSMENTS AND ESTIMATES

### RECOVERY OF VALUE OF DEVELOPMENT EXPENDITURE

There are no indications of further impairment requirements as at December 31, 2020. 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 15.

## NOTE 35. RECONCILIATION OF ALTERNATIVE PERFORMANCE MEASURES

For definitions of performance measures, see page 74

### EBITDA

SEK thousands	2020	2019
<b>Operating income</b>	<b>-45 675</b>	<b>3 940</b>
Amortization and impairment of intangible assets	17 685	14 539
Depreciation and impairment of tangible assets	12 353	10 321
<b>EBITDA (Operating income before depreciation and amortization)</b>	<b>-15 637</b>	<b>28 800</b>

### BRUTTOMARGINAL

SEK thousands	2020	2019
<i>Operating income</i>		
Net sales	179 861	220 837
Operating expenses		
Cost of goods sold	-46 886	-58 024
<b>Gross income</b>	<b>132 975</b>	<b>162 813</b>
<b>Gross margin %</b>	<b>74</b>	<b>74</b>

### Gross margin, non-durable goods

<i>Operating income</i>		
Net sales of non-durable goods	169 425	206 857
Operating expenses		
Cost of non-durable goods sold	-38 980	-47 439
<b>Gross income, non-durable goods</b>	<b>130 445</b>	<b>159 418</b>
<b>Gross margin, non-durable goods %</b>	<b>77</b>	<b>77</b>

### EQUITY/ASSETS RATIO

SEK thousands	201231	191231
Shareholders' equity	1 008 461	577 521
Total assets	1 150 309	634 487
<b>Equity/assets ratio %</b>	<b>88</b>	<b>91</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 July 19, 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 March 29, 2021. 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 22, 2021.

March 29, 2021  
Gothenburg

Gösta Johannesson  
Chairman of the board

Dag Andersson  
CEO

Folke Nilsson  
Boardmember

Camilla Öberg  
Boardmember

Yvonne Mårtensson  
Boardmember

Lars Henriksson  
Boardmember

Lena Höglund  
Boardmember

Our audit report was issued on March 29, 2021

KPMG AB

Daniel Haglund  
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 2020, except for the corporate governance statement on pages 48-51. The annual accounts and consolidated accounts of the company are included on pages 42-68 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 2020 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 2020 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 48-51. 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 pages 58-60 in the annual account and consolidated accounts for detailed information and description of the matter.

#### Description of key audit matter

Revenue for 2020 in the Group amounted to 179,9 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 CAPITALIZED EXPENDITURE FOR DEVELOPMENT

See disclosure 15 and accounting principles on page 59 in the annual account and consolidated accounts for detailed information and description of the matter.

#### Description of key audit matter

As of 31 December 2020, the Group reported goodwill of SEK 223,9 million and capitalized development costs of SEK 394 million, representing 54% 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 operations in perfadex sales and the acquisition of Organ Assist. Capitalized expenses for development work mainly pertain to the operations within heart transplantation, sales of XPS and STEEN Solution in the US market as well as acquired assets relating to the kidney and liver areas identified in connection with the acquisition of Organ Assist.

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 404,5 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 42-68. 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.

## AUDITOR'S 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 2020 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 48-51 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 29 March 2021

KPMG AB

(Signature on the original document)

Daniel Haglund  
Authorized Public Accountant

# BOARD OF DIRECTORS



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

Born 1959, MBA from Uppsala University. Senior advisor at Bure Equity AB.

Other assignments: Deputy Chairman of Interflora AB, board member of Mentice AB, Scandinova Systems AB and Yubico AB. Gösta Johannesson was previously a partner in Provider Venture Partners, before that in leading positions within Öhman Fondkommission and Handelsbanken Markets. Gösta Johannesson is dependent on the company's major owners. Gösta Johannesson has been a board member of the company since 2013.

Shareholding in XVIVO Perfusion: 2,000 shares



**Folke Nilsson**

Born 1950, trained doctor and Thoracic surgeon.

Previously responsible for the Heart and Lung Transplant operations at Sahlgrenska University Hospital and is currently working as a general practitioner. No other board assignments. Folke Nilsson is independent of the company and the company's major owners. Folke Nilsson has been a board member of the company since 2013.

Shareholding in XVIVO Perfusion: 0 shares.



**Camilla Öberg**

Born 1964, MBA from the Stockholm School of Economics. Chief Financial Officer at Yubico AB.

Other assignments: Board member of Instalco Intressenter AB. Former CFO at Cybercom Group AB and Logica Sweden, leading positions in WM-data, Swegro Group and Lexicon. Camilla Öberg is independent in relation to the company and the company's major owners. Camilla Öberg has been a board member of the company since 2016.

Shareholding in XVIVO Perfusion: 1,076 shares.



**Yvonne Mårtensson**

Born 1953, MSc from the Institute of Technology at Linköping University. Thirty years' experience from medtech companies such as Viggo, Hemocue and Cellavision.

Other assignments: Chairman of the Board of Elos Medtech AB and member of the board of Lystone A/S. Former CEO of CellaVision AB during the years 1998-2014. Yvonne Mårtensson is independent in relation to the company and the company's major owners. Yvonne Mårtensson has been a board member of the company since 2018.

Shareholding in XVIVO Perfusion: 3,000 shares.



**Lena Höglund**

Born 1960, management training at The Centre for Outstanding Leadership AB, Stockholm and Management Centre Europé, Bryssel. VP Clinical Marketing Neuro Solutions. Thirty years' experience from leading commercial positions at Elekta.

Other board assignments: Chairman of Leksell Gamma Knife Society and board member at Bergvik Group AB. Lena Höglund is independent in relation to the company and the company's major owners. Lena Höglund has been a board member of the company since 2020.

Shareholding in XVIVO Perfusion: 0 shares



**Lars Henriksson**

Born 1955. DDM at Gothenburg University. Over thirty years' experience from medtech companies such as Astra Tech and Dentsply Sirona.

Other Board assignments: Board member at AddBio. Lars Henriksson is independent in relation to the company and the company's major owners. Lars Henriksson has been a board member of the company since 2020.

Shareholding in XVIVO Perfusion: 900 shares

## AUDITORS

The company's auditor is KPMG AB. The principal auditor is Authorized Public Accountant Daniel Haglund (born 1974).

KPMG AB Visiting 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



Johan Holmström  
CCO

Charlotte Walldal  
Global research and  
development director

Christoffer Rosenblad  
COO and Deputy CEO

Dag Andersson  
CEO

Kristoffer Nordström  
CFO

Katrin Gisselfält  
Global QA & RA Director

Andreas Wallinder  
CMO

## **Dag Andersson** CEO

Born 1961, MBA from INSEAD and a B.A. (Hons) in Business and Commerce from Stockholm School of Economics. Long experience from the MedTech and life science industry, most recently from the role as CEO for Diaverum AB 2008-2018, and before that leading positions at Mölnlycke Health Care AB 1993 – 2007. Other assignments: Board member in GHP AB and Terveystalo Oy.

Shareholding in XVIVO Perfusion: 54 392 shares and 34 000 warrants

## **Christoffer Rosenblad** COO and 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. Other assignments: Board member in Sedana Medical AB.

Shareholding in XVIVO Perfusion: 54 392 shares and 39 000 Warrants

## **Kristoffer Nordström** CFO

Born 1985, M.Sc. Business and Economics from University of Borås. Previously Head of Accounting and Controlling at XVIVO Perfusion. 10 years of experience as Authorized Public Accountant and Senior Manager at KPMG Sweden.

Shareholding in XVIVO Perfusion: 500 shares and 17 000 warrants.

## **Johan Holmström** CCO (Chief Commercial Officer)

Born 1970, M.Sc. Business Administration and Finance at University of Gothenburg. Previously Executive VP Marketing at Permobil, before that various senior management positions within sales, marketing and business development at Lohmann & Rauscher and Mölnlycke Health Care.

Shareholding in XVIVO Perfusion: 1000 shares and 16 000 warrants.

## **Charlotte Walldal** Global research and development director

Born 1967, M.Sc. Chemistry. Eng. at Chalmers University of Technology and Ph.D Physical Chemistry. at University of Gothenburg. Previously VP R&D Personal Care at Essity and before that management positions within development and innovation.

Shareholding in XVIVO Perfusion: 0 shares and 16 000 warrants.

## **Andreas Wallinder** CMO (Chief Medical Officer)

Born 1977, Doctor of Medicine from Karolinska Institutet. Board exam in Cardiothoracic surgery. PhD in Lung Transplantation at University of Gothenburg. Previously Consultant Cardiothoracic Surgeon at Sahlgrenska University Hospital and before that Cardiothoracic Surgery Fellow at Alfred Health, Melbourne.

Shareholding in XVIVO Perfusion: 0 shares and 34 000 warrants.

## **Katrin Gisselfält** Global QA & RA Director (Quality Assurance & Regulatory affairs)

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 and 30 000 warrants.

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:

## Evaluation

Evaluation of the function of an organ.

## 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.

## EVLV 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.

## 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.

## Hypothermic non-ischemic perfusion of heart

Circulation of the cooled, dormant donated heart with the supply of oxygen and necessary nutrients during transport to the recipient.

## In vivo

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

## Clinical study/trial

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

## Machine perfusion

New technology that improves preservation and evaluation of organs, which means more organs can be used for transplants. Within the business area Thoracic this includes STEEN Solution™, XPST™, LS™, Lung Assist and Heart Assist as well as other products and services related to the use of those products. Within the business area Abdominal this includes Kidney Assist Transport, Kidney Assist and Liver Assist as well as other products and services related to the use of those machines.

## 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.

## 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.

## Perfusion

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

## 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.

## 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.

## Preservation

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

## 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).

## Static preservation

Static preservation refers to preservation methods where the organ is kept cold during transport and before transplantation. Within the business area Thoracic this includes Perfadex® Plus as well as other products and services related to the use of that product.

# DEFINITIONS

KPI	DEFINITION	MOTIVATION
<b>Gross margin, non-durable goods, %</b>	Gross income for the period segment all non-durable goods divided by the period's net sales segment all non-durable goods.	The company believes that this key figure provides an in-depth understanding of the Company's profitability regarding its non-durable goods operations. Since the pricing strategy for durable goods differs from the pricing strategy for all other operations, the gross margin is reported separately for non-durable goods.
<b>Gross margin, %</b>	Gross income for the period divided by net sales for the period.	The company believes that this key figure provides an in-depth understanding of the Company's profitability.
<b>EBITDA margin, %</b>	EBITDA (Operating income before depreciation and amortization for the period) divided by the period's net sales.	The company believes that this key figure provides an in-depth understanding of the Company's profitability.
<b>Operating margin, %</b>	Operating income for the period divided by the period's net sales.	The company believes that this key figure provides an in-depth understanding of the Company's profitability.
<b>Net margin, %</b>	Profit of the period divided by net sales of the period.	The company believes that this key figure provides an in-depth understanding of the Company's profitability.
<b>Equity/assets ratio, %</b>	Shareholders' equity divided by balance sheet total.	The equity/assets ratio shows the size of equity in relation to the balance sheet total and has been included to give investors a picture of the Company's capital structure.
<b>Equity per share, SEK</b>	Shareholders' equity divided by the number of shares outstanding on the balance sheet date.	This key figure has been included to give investors an overview of how the Company's equity per share has developed.
<b>Earnings per share, SEK</b>	Profit for the period divided by the average number of shares, before dilution, for the period.	This key figure has been included to give investors an overview of each period's dividends.
<b>Earnings per share after dilution, SEK</b>	Profit for the period divided by the average number of shares, after dilution, for the period.	This key figure has been included to give investors an overview of how the Company's share price has developed.







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

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