

# AGM 2019 – CEO MAGNUS NILSSON

*“We believe NO ONE SHOULD HAVE  
TO DIE WAITING FOR A NEW ORGAN”*

April 25, 2019

# Summary of XVIVO Perfusion

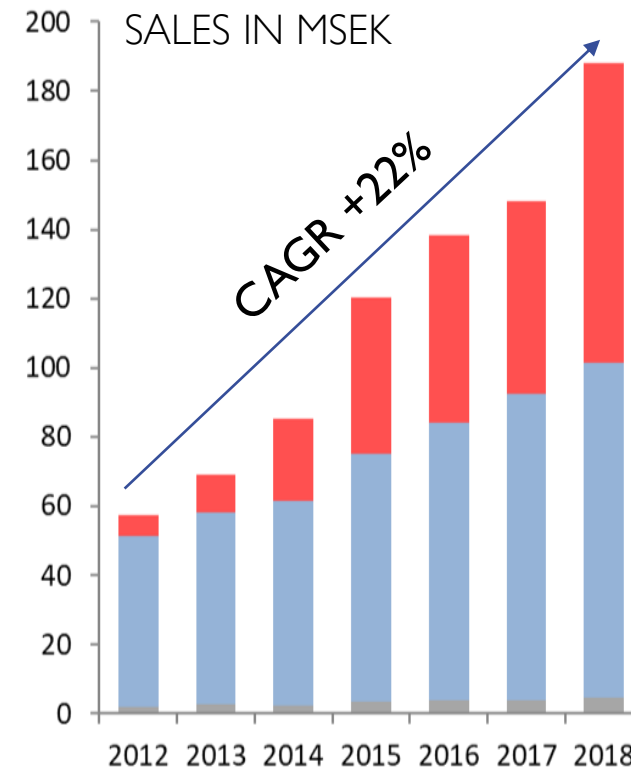
## High market demand

– Currently only 10% of need met\*

**XVIVO has an Unique Patented, Approved and Documented technology** for making more organs available

**XVIVO market leader in Lung Tx** and the only supplier with FDA approval for warm perfusion of marginal Lungs ex-vivo

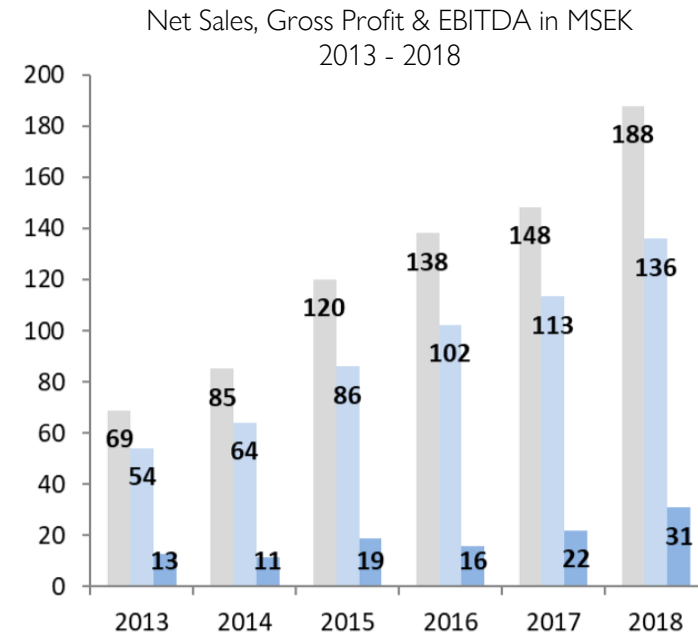
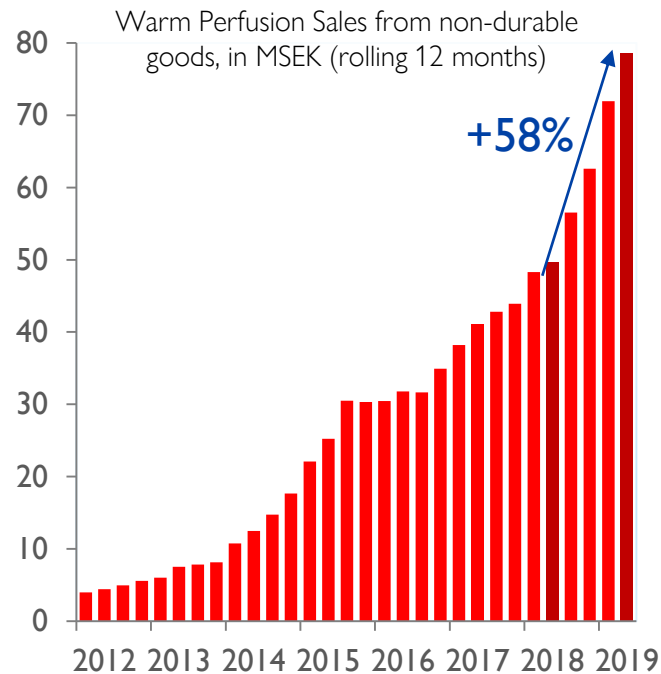
**Strong R&D pipeline for future growth**  
Several product dev. project in clinical phase



\* Data from GODT

# XVIVO performance

- Sales growth from warm perfusion products, last 12 months +58%
- EBITDA positive during high investments in Development and M&S
- Profitable growth every quarter since 2003



# XVIVO invests for future growth

XVIVO invests in development of IP protected unique products with the vision that nobody should die waiting for an organ.

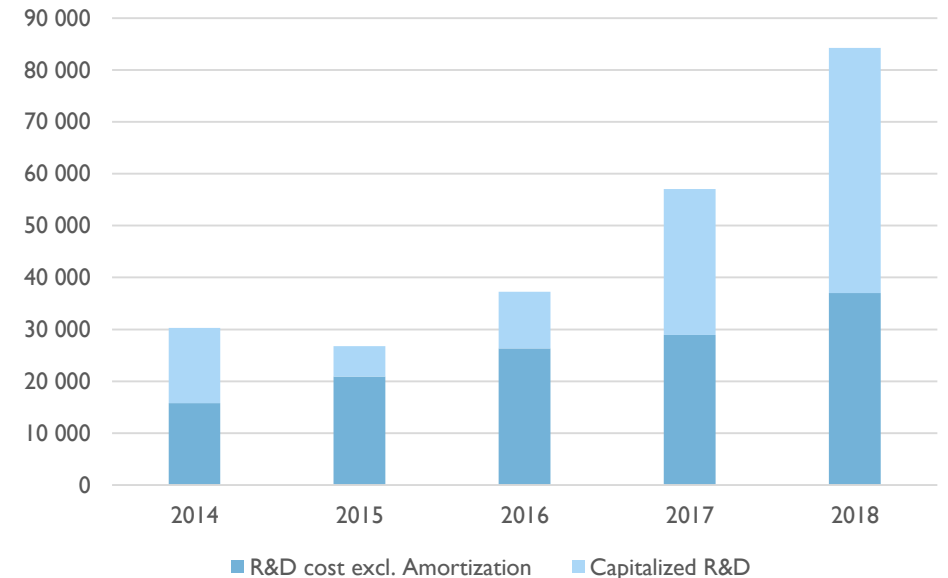
## R&D cost excl. amortization – 2014/2018 CAGR 24%

Development of the existing product portfolio e.g. new features on the XPS, EVLP clinical studies, Steen Solution for abdominal organs etc.

## Capitalized R&D – 2014/2018 CAGR 34%

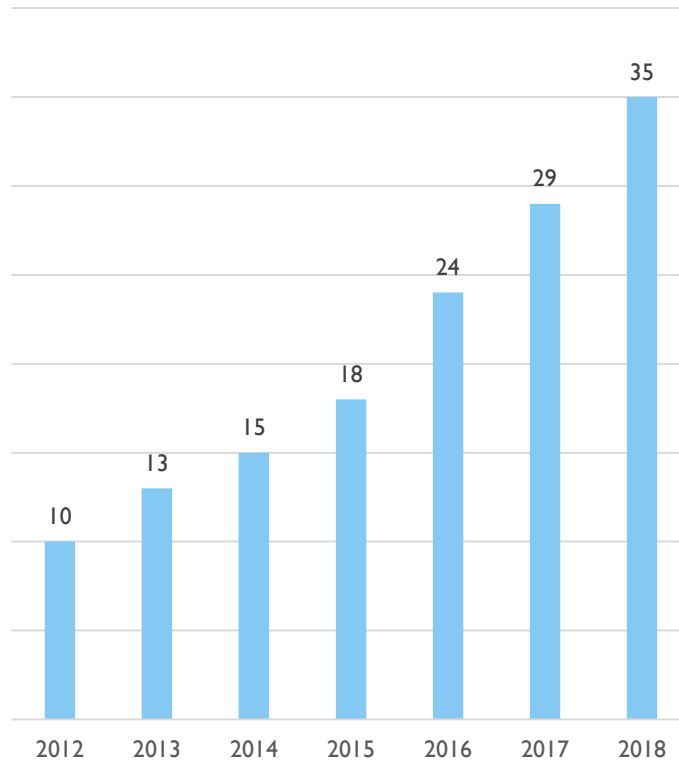
Development and regulatory approval of new products e.g. FDA approval of XPS and STEEN Solution, Heart preservation project, and PrimECC

In thousand SEK



# A growing & diverse organization

Average number of employees



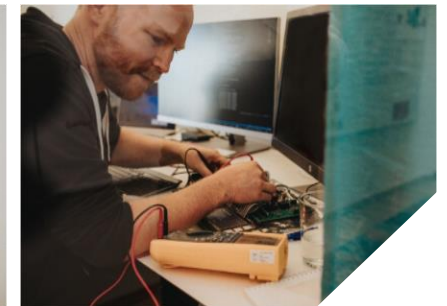
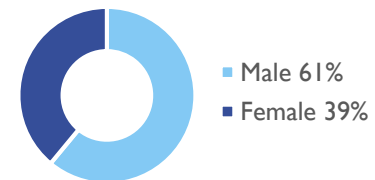
Employees per location



Employees per function



Employees by gender

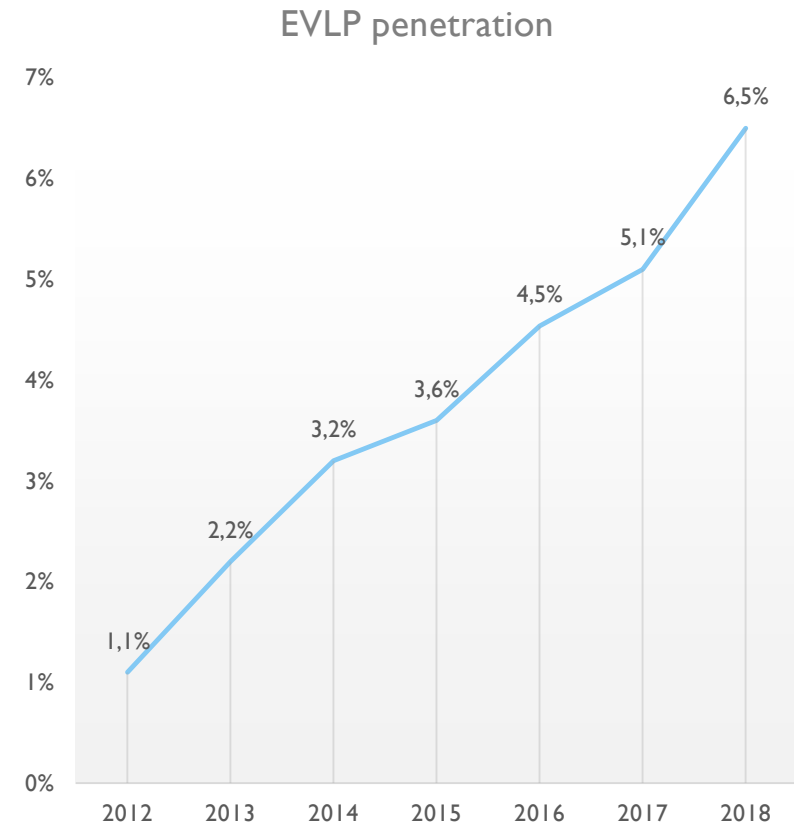


# Development of EVLP on the total market\*

In 2018 an estimated 6 300 lungs were transplanted world wide

Around 400 of those lungs came from EVLP

EVLP market penetration is estimated to 6,5%, up from estimated 1,1% in 2012

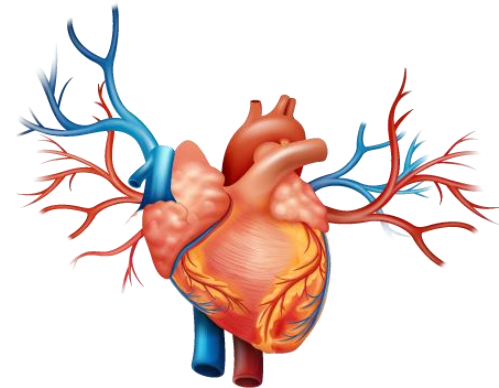
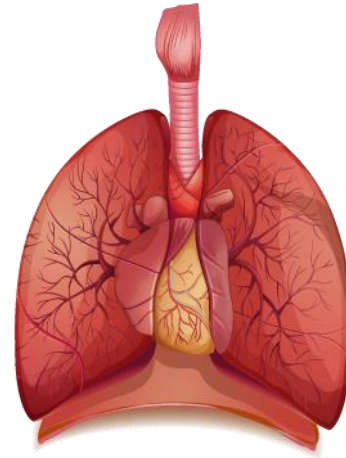


\* Estimated by XVIVO

# Highlights 2018

- Net Sales grew +27% (+23% in LC\*)
- Strong growth for non-durable Warm perfusion sales +48%
- PMA application for STEEN Solution™ and XPS™ submitted to the FDA
- The PrimECC® study shows that the product is safe and displays positive clinical results
- United Therapeutics and XVIVO Perfusion initiated collaboration on EVLP

\* Local currency



# PERFADEX® PLUS launch in 2018

A ready to use Perfadex® with increased patient safety and customer convenience

Successfully launched in Europe and USA

Well received by customers and clinicians

Ready to use and click port – reduced complexity and preparation time while increasing patient safety

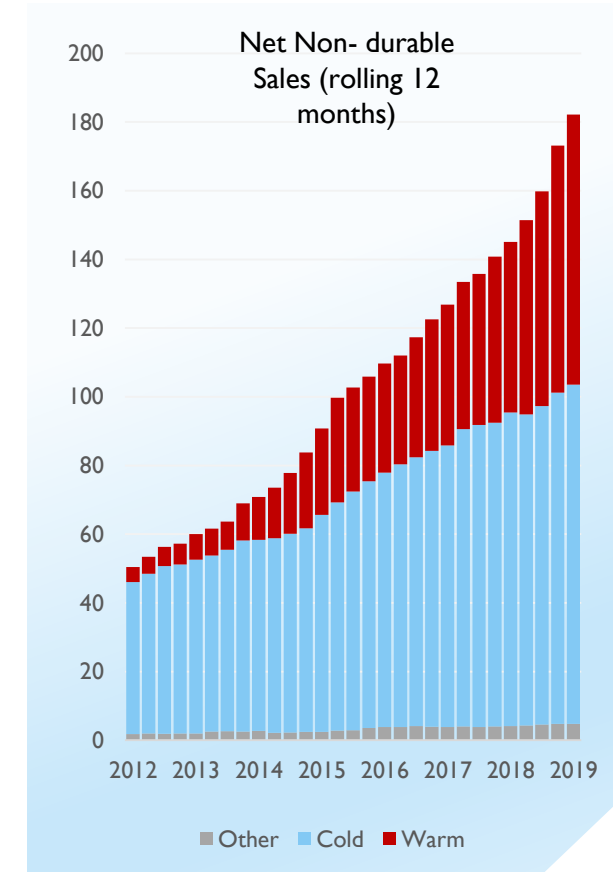
Patent applications filed



2019 – Q1

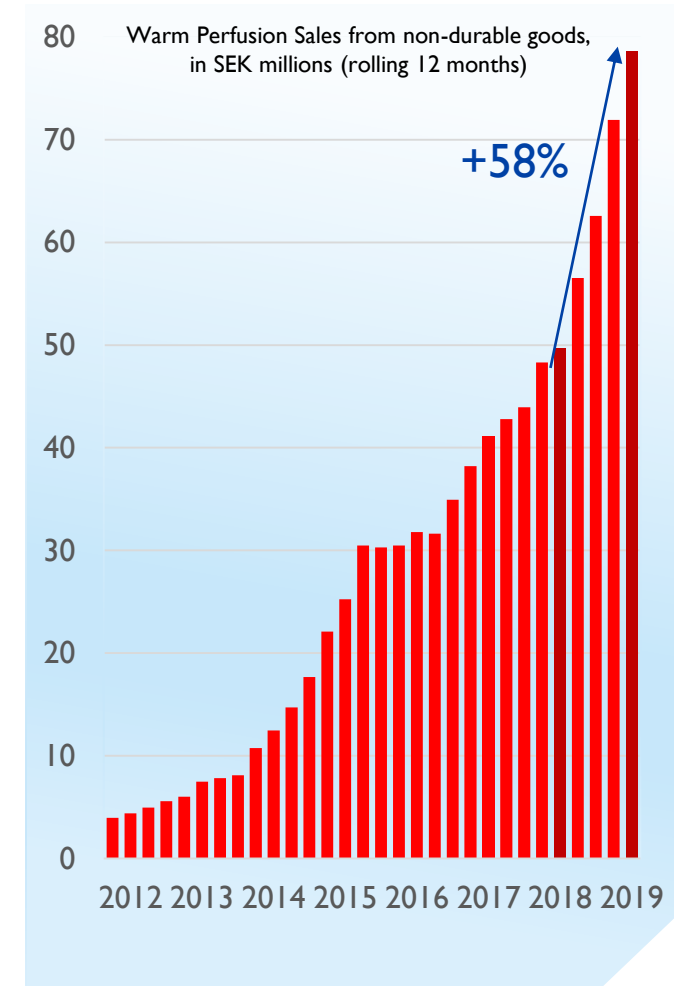
# Highlights 2019 - Q1

- Reimbursement for the whole EVLP process approved in France
- Results from first six patients in the heart preservation study were presented during ISHLT showing that the method is safe
- High interest from to the world's leading heart transplant surgeons after XVIVO Perfusion's heart preservation machine was showed for the first time
- Continued strong EBITDA even though high investments in organizational capacity and research



# Sales highlights 2019 - Q1

- Net Sales non-durable goods +24% (+13% in LC\*)
- Warm non-durable growth +52% (+40% in LC\*)
- Warm non-durable growth rolling 12 month + 58% (YoY)



\* Local currency

# Profit & loss

Non-durable Sales +24%

Continued high Gross Margin

Continued customer support build up

R&D clinical and product development build up

Lung Tx business profitable despite high investments in Marketing and R&D

(SEK Millions)	2019 Jan-Mar	2018 Jan-Mar	2018 Full year
Net sales	47.6	42.5	187.9
Net sales non-Durable goods	46.8	37.9	172.7
Gross profit	36.9	30.1	136.0
Gross Margin %	77%	71%	72%
Gross Margin non-Durable goods %	77%	77%	77%
Selling expenses %	-25%	-24%	-26%
Admin. expenses %	-11%	-11%	-12%
R&D exp. excl. Amort. ** %	-25%	-21%	-20%
Items effecting comparability * %	-12%	0%	0%
R&D Amortization ** %	-6%	-6%	-6%
Other expenses excl. Items effecting comp. * %	-2%	-1%	-2%
Operating Result %	-4%	7%	7%
Operating Result * %	8%	7%	7%
EBITDA excl. items effecting comperability	8.8	7.2	30.9
EBITDA excl. items effecting comperability %	18%	17%	16%
EBITDA	3.2	7.2	30.9
EBITDA %	7%	17%	16%

Items effecting comparability are **5.5 MSEK** due to the increased share price. The AGM 2017 and 2018 approved a share based bonus program to employees outside Sweden, mirroring the Swedish warrant program.

\*Items effecting comparability: 5.5 (0.0) MSEK.

\*\*R&D Amortization: 3.0 (2.7) MSEK.

# ISHLT\* 2019

## Increasing interest for EVLP and the new Heart preservation technology

- High and increasing interest for clinical EVLP
  - » Utilization of DCD\*\* & Hep. C donors
  - » Protective ventilation during EVLP
  - » Immunology in EVLP
- Excitement for XVIVO's new heart technology
  - » Prof Stig Steen presented his groundbreaking research
  - » Prof Johan Nilsson (Lund) presented the good results from the first six heart machine patients



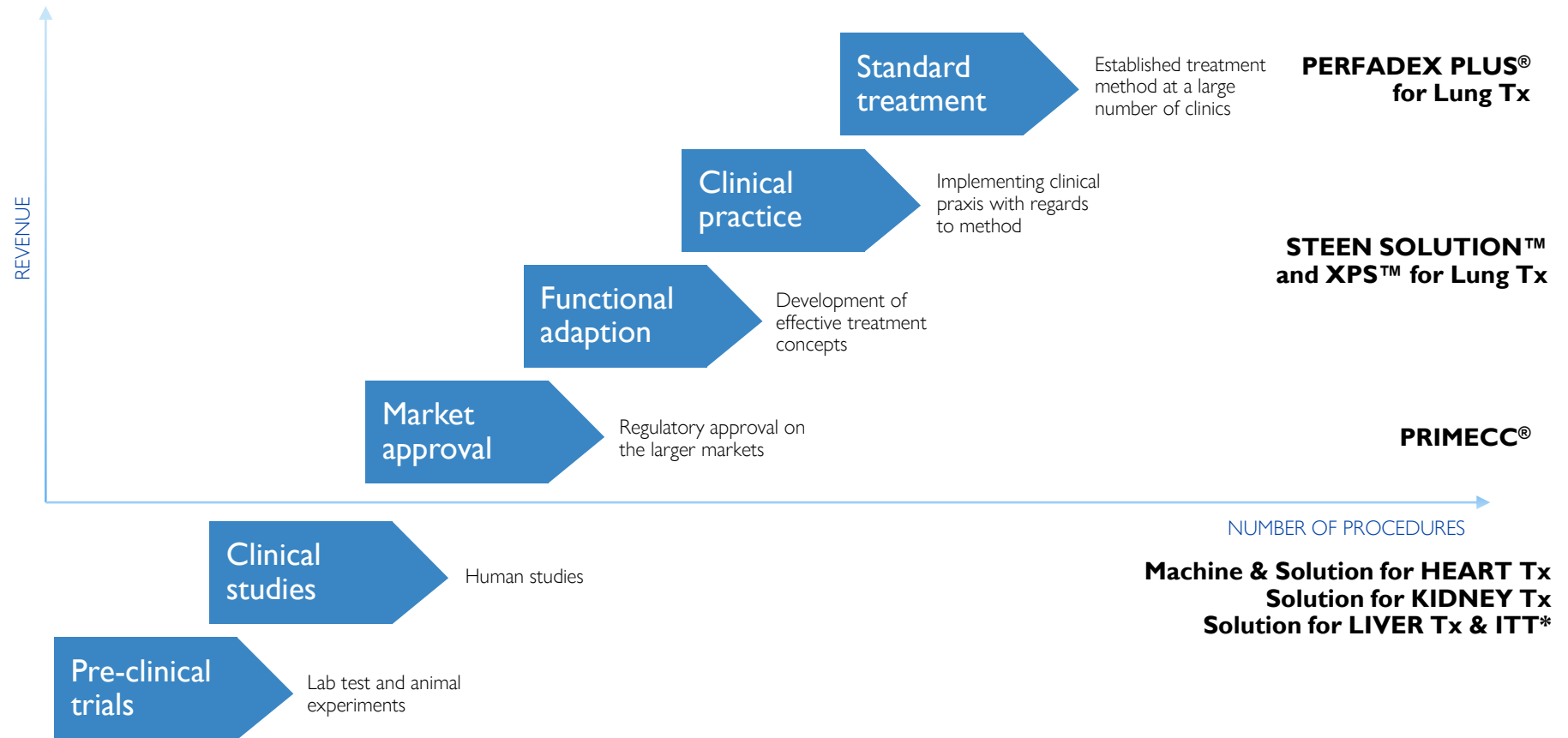
\*International Society for Heart & Lung Transplantation

\*\* DCD = Donation after Cardiac or Circulatory Death



THE R&D PIPELINE  
- TO ENSURE FUTURE GROWTH

# Typical development steps – Medical device Class III



\* ITT or Isolated Tissue Therapy is a therapy where one part of the body is isolated for treatment in order to avoid side effects.

# XVIVO enable future growth within lung transplantation

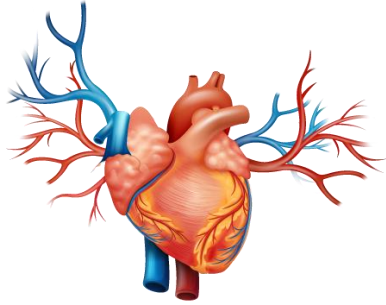
XVIVO will continue to clinically develop EVLP:

- Expanded use of DCD\* lungs for transplantation
- Ex vivo infection therapy e.g. Pneumonia therapy and virus reduction
- EVLP protocol development
- Investigate immunological response during EVLP targeting short term organ function & long term survival
- Continued development of the XPS™ to enable online parameters for better decision making.



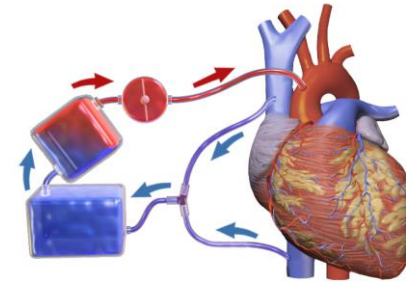
\*Donation after Circulatory Death

# XVIVO – The R&D pipeline



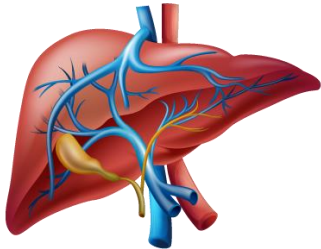
Priority 1

**Heart Transplant project**, optimized preservation to prolong time outside the body



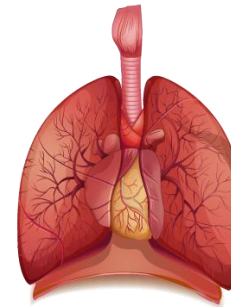
Priority 2

**PrimECC®**, optimized priming solution to reduce known side effects



Priority 3

**STEEN Solution™** for Liver and Kidney Transplant, evaluation of marginal and DCD organs



Priority 4

**ITT\*** – Perfusion of isolated organs / tissues (e.g. Drug administration) with STEEN Solution™

\*Isolated Tissue Therapy

# XVIVO - Heart transplantation

Heart perfusion and preservation solution and device developed by Prof. Steen

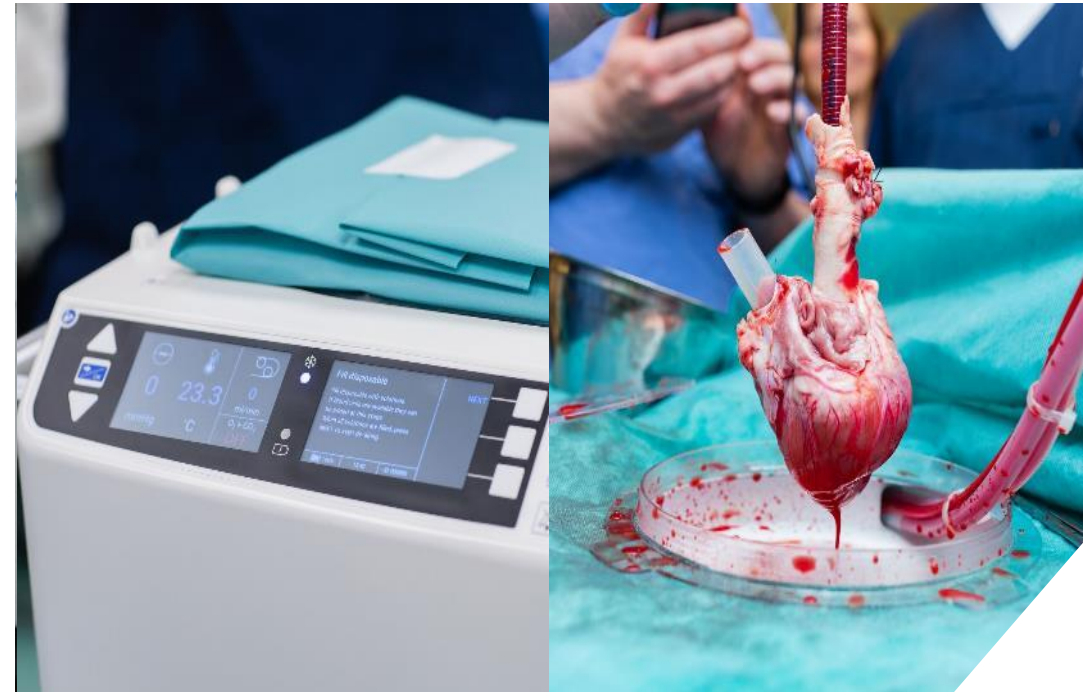
Development stage:  
Early Clinical Phase

Pre-clinical proof of concept studies indicate:

- » No non-oxygenated time → Better organ quality
- » Longer preservation time possible (24h in pigs)
- » Pig to Monkey transplant 6 month survival study

Results from the clinical safety study at Lund University Hospital on 6 patients indicate:

- » Hearts can be safely preserved with the NIHP\* method resulting in successful transplantation
- » Reduced risk for ischemic induced reperfusion injury



\*Non ischemic heart preservation

# XVIVO - Heart transplantation

Development stage:  
Early Clinical Phase

## QI Accomplishments

Pre-clinical and technical testing successfully performed

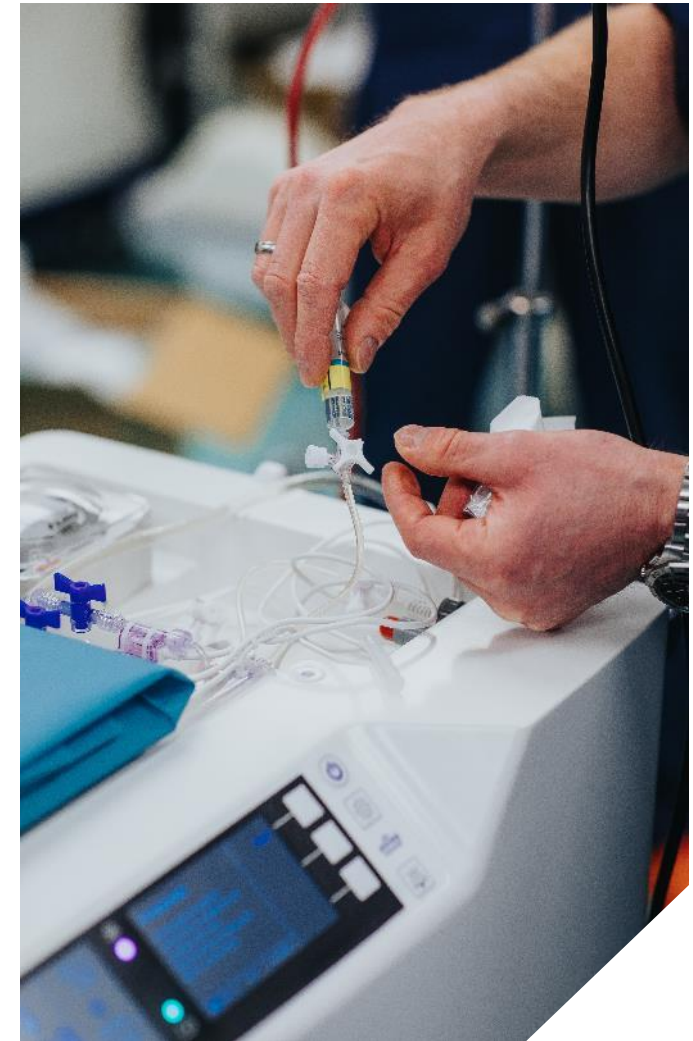
XVIVO Perfusion's heart preservation machine demonstrated

→ High interest from leading heart transplant surgeons worldwide

## Next steps

Production ramp up of machine, disposable and solution

Clinical trial preparation in Europe, Australia and the US



Serval hundred thousand operations using a heart-lung machine are performed each year. PrimECC® is developed to prime the heart-lung machine before open heart surgery.

## Accomplishments

- Patented
- CE marked
- Clinical study with 40+40 patients showed
  - PrimECC® is safe to use
  - Improved fluid balance and reduction of side effects using a heart-lung machine primed with PrimECC®

## Ongoing tasks

- Setup of large scale production in eco friendly bags
  - Validation batch planned for Q2
- Preparation for clinical documentation program
  - High interest from clinics that will participate in multicenter study

# Outlook 2019 - Focus areas

## **Thoracic Transplantation / Surgery (Primary focus)**

- Lungs – Further develop the EVLP technology
- Heart – Preparation for multicenter study for regulatory approval on all major markets
- PrimECC® – Preparation for multicenter study for clinical documentation

## **Abdominal Transplantation & new indications (Secondary focus)**

- Continued support for clinical development of Liver Tx and Kidney Tx with STEEN Solution technology

## **Long-term goals**

- Solidify position in Thorax surgery (Lung Tx, Heart Tx, PrimECC ®)
- Build a new business using the STEEN Solution™ technology in Liver and Kidney Tx

A photograph showing the back of a person in a white hospital gown with a small dark pattern. They are being supported from behind by a person with curly hair wearing a blue long-sleeved shirt. They are both looking out a window with white curtains. The image has a blue geometric overlay in the top right corner.

THANK YOU!