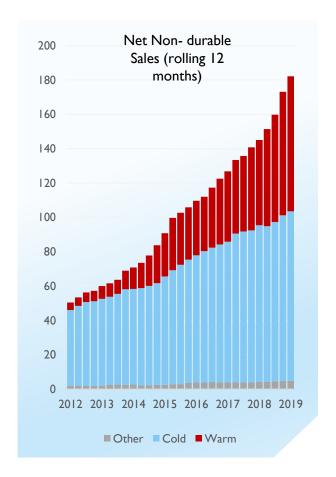


## Highlights 2019 - QI

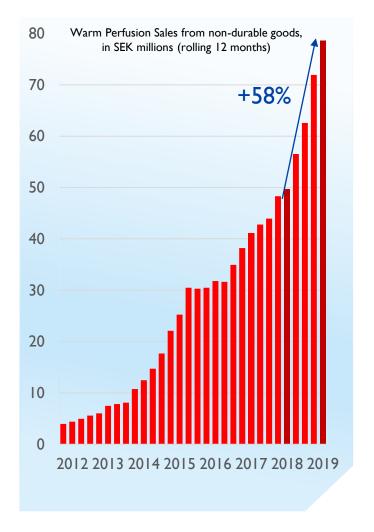
- Reimbursement for the whole EVLP process approved in France
- Results from first six patients in the heart preservation study were presented during ISHLT showing that the method is safe
- High interest from to the world's leading heart transplant surgeons after XVIVO Perfusion's heart preservation 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)







### 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

	2019	2018	2018
(SEK Millions)	Jan-Mar	Jan-Mar	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



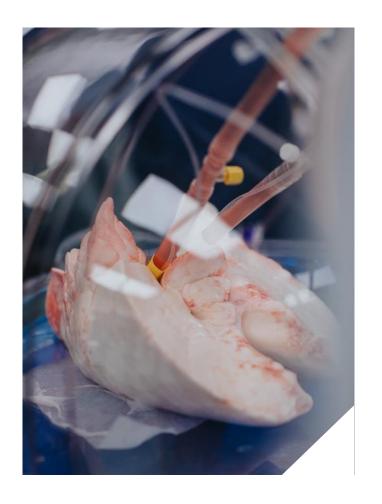


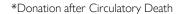


## XVIVO enable future growth within lung transplantation

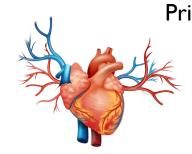
XVIVO will continue to clinically develop EVLP:

- 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<sup>™</sup> to enable online parameters for better decision making.



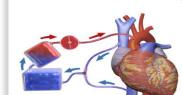


## XVIVO – The R&D pipeline



#### Priority I

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™

# XVIVO - Heart transplantation



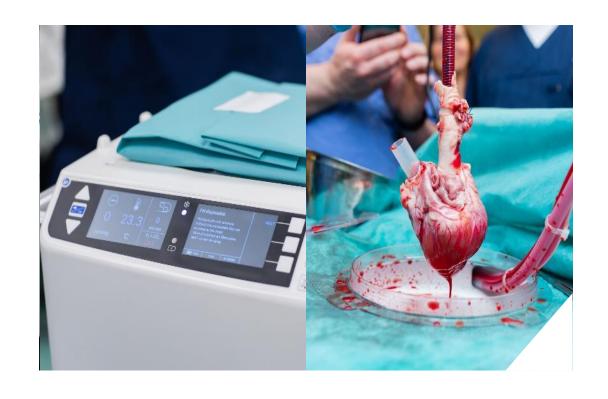
#### Heart perfusion and preservation solution and device developed by Prof. Steen

#### 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



<sup>\*</sup>Non ischemic heart preservation

### XVIVO - Heart transplantation

#### Q1 Accomplishments

Pre-clinical and technical testing successfully performed

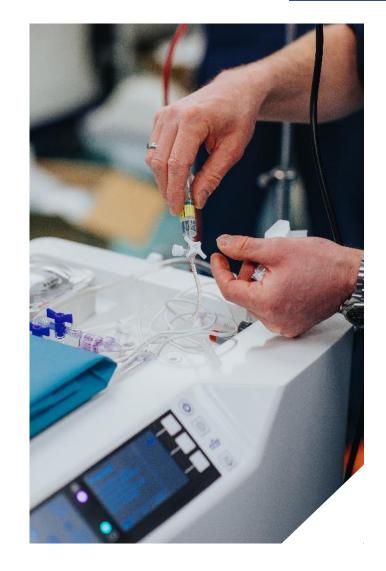
XVIVO Perfusion's heart preservation machine demonstrated

→ 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





### **PRIMECC®**

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
  - o PrimECC® is safe to use
  - o Improved fluid balance and reduction of side effects using a heart-lung machine primed with PrimECC®

#### Ongoing tasks

- Setup of large scale production in ecofriendly bags
  - o Validation batch planned for Q2
- Preparation for clinical documentation program
  - o 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



