

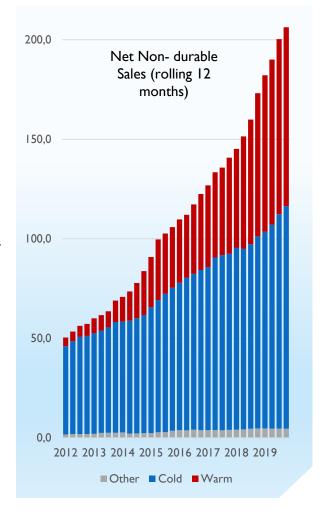
## A historic year ended with a record quarter

### Q4

- » Breakthrough Device Designation granted from the FDA for the XVIVO Heart Preservation System
- » An Australian subsidiary was established subsequent of third XPS installation

#### 2019

- » Submission of applications of clinical trials for Heart device and updated technical file of PrimECC
- » PMA from the FDA (USA) for the products XPS™ and STEEN Solution™
- » Perfadex® Plus patent approved in Europe
- Patents for the heart preservation fluid approved in the US and Europe
- » Positive results from the clinical safety study at Lund University Hospital on 6 patients
- » Two year warranty program, offered to all employees were fully subscribed with strike price of 279 SEK





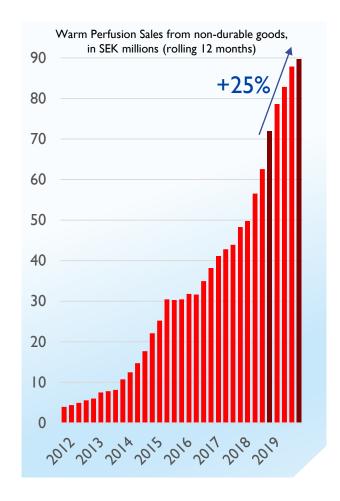
## Sales highlights 2019 – Record sales quarter

### Q4

- » Record sales in quarter, compared with a strong Q4 last year
  - Non-durable sales +14%
- » Continued stable gross margin of non-durable goods during growth, 77%

#### 2019

- » Continued strong sales of non-durable goods, +20%
- » Net sales of non-durable goods passed 200 MSEK for the first time
- » Warm non-durable growth, + 25%
- Continuation of positive sales trend for Cold preservation, +16%





## **Profit & loss**

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
(SEK Millions)	Jan-Dec	Jan-Dec
Net sales	220.8	187.9
Net sales non-Durable goods	206.9	172.7
Gross profit	162.8	136,0
Gross Margin %	74%	72%
Gross Margin non-Durable goods %	77%	77%
Selling expenses %	-28%	-26%
Admin. expenses %	-11%	-12%
R&D exp. excl. Amort. ** %	-21%	-20%
Items effecting comp. * %	-3%	-1%
R&D Amortization ** %	-8%	-6%
Other expenses excl. Items effecting comp. * %	-2%	-2%
Operating Result %	2%	7%
Operating Result * %	5%	9%
EBITDA excl. items effecting comperability	35.8	33.7
EBITDA excl. items effecting comperability %	16%	18%
EBITDA	28.8	30.9
EBITDA %	13%	16%

Items effecting comparability are **7.0 MSEK** due to the increased share price. The AGM 2017-2019 approved a share based bonus program to employees outside Sweden, mirroring the Swedish warrant program.

\*Items effecting comparability: 7.0 (2.8) MSEK.



<sup>\*\*</sup>R&D Amortization: 16.6 (10.9) MSEK.



## PMA approval from the FDA

XVIVO received FDA approval (PMA) for XPS™ and STEEN Solution™

### Multicenter study showing that

- » 110 Initially not accepted lungs were transplanted after EVLP evaluation deemed them transplantable
- » 1 and 2 year survival rate similar to initially accepted lungs (US-data UNOS)
- » Higher use rate of DCD-lungs possible
  - → More lungs can be used for transplant which will benefit patients on the waiting list



## Breakthrough Device Designation' granted by FDA for XHPS

Breakthrough designation will shorten the administration time for the whole study process and for the application for market approval in the US.

This means a decreases time to market.

The Breakthrough Devices Program by the FDA is a mean for the FDA to prioritize those Medical devices that is deemed especially important to patients by speeding up their development, assessment, and review of medical devices, while preserving the statutory standards for premarket approval(PMA), 510(k) clearance, and De Novo marketing authorization.





## Increased presence in fast growing Chinese transplant market

China currently shows the fastest growth in the world with a 35 percent increase in lung transplants in 2018

- » With 403 lung transplants performed in 2018
- » Sales increase of +355% between 2018 and 2019

XVIVO Perfusion has sold an XPS™ to the second largest lung transplant clinic in China, the China-Japan Friendship Hospital, in Beijing

- » The lung transplant program lead by Professor Jingyu Chen, KOL in China.
  - > 107 lung transplants in 2018 compared to 3 in 2016



## The upgraded ready to use Perfadex® Plus patented in Europe

XVIVO Perfusion has received European patent approval for the company's ready to use product Perfadex® Plus for cold preservation of lungs.

- » Perfadex® Plus was launched in Europe and the US in 2018.
- » A ready to use Perfadex with increased patient safety and customer convenience
- » Patent applications have been submitted in all relevant markets.





## Deepened cooperation with Lung Bioengineering

Lung Bioengineering offer EVLP service to clinics in the US using XVIVO technology and products

- » Currently 2 XPS in Lung Bioengineering (subsidiary of United Therapeutics) Maryland EVLP center
- » In August 2019 Lung Bioengineering purchased the first XPS for their Jacksonville EVLP center
- » XVIVO and Lung Bioengineering are cooperating in Marketing their EVLP service to US-clinics
- » Collaboration in the area of Xeno-transplantation with XVIVO's heart preservation technology











## Investment in future EVLP growth

### Continued XPS development of online parameters improving decision making.

- » Sensors for weight, blood gases, metabolites etc.
- » Biomarker project

### Expanded use of DCD\* lungs for transplantation

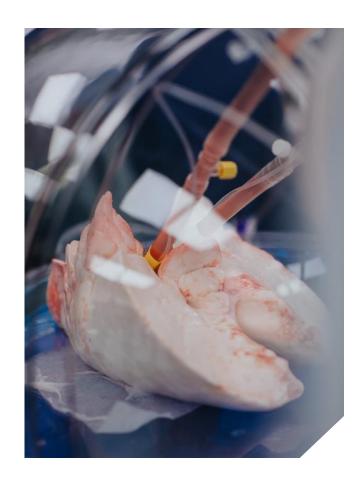
» Clinical research on Controlled/Uncontrolled DCD

### Continued EVLP protocol development

» Ventilation strategy, organ proneing etc.

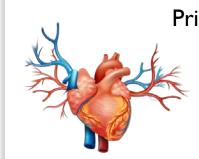
### Investigating immunological response during EVLP

» Targeting short term organ function & long term survival





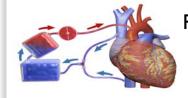
## XVIVO – The R&D pipeline



## Priority I

Heart Transplant project, optimized preservation to sustain organ quality





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™



<sup>\*</sup>Isolated Tissue Therapy

#### Development stage: Early Clinical Phase

## XVIVO - Heart transplantation

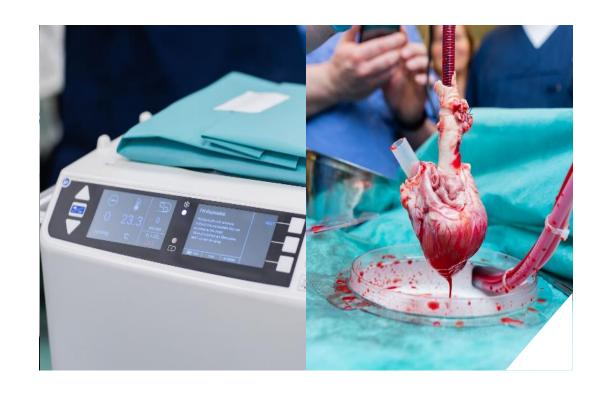
## Heart perfusion and preservation solution and device developed by Prof. Steen

### Pre-clinical proof of concept studies indicate:

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

# The ongoing clinical study at Lund University Hospital with result on first 6 patients after 6 months indicate:

- » Hearts can be safely preserved with Prof. Steen's NIHP\* technology resulting in successful transplantation
- » Reduced risk for ischemic induced reperfusion injury







# XVIVO - Heart transplantation - Accomplishments

- » Heart Preservation System (XHPS) has been granted 'Breakthrough Device Designation' from the FDA – shorting time to market
- » Patents for the heart preservation fluid approved in the US and Europe
- » Clinical team buildup, machine, disposables and solution design finalized, tested and production validated and the ramped up
- » Ongoing preparations for multi-center trials in Europe, US and Australia centers recruited
- » Applications submitted and interaction with regulatory authorities ongoing
- » The European multi-center trial is expected to be the first to start (Q1) and depending on authority approvals the others subsequently









## PRIMECC® - Background

Priming solutions are used to prepare the heart-lung machines before employed in open heart surgery. This solution enters the patient at the start of the procedure

- » The solutions used today are not optimized and are known to cause side-effects.
- » 600-700 thousand bags are used each year when running heart-lung machines in open heart surgery.
- » PrimECC® is developed to alleviate known side effects





## PrimECC® - Development status

### **Accomplishments**

- Patented in EU, USA, China, Japan
- 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®
- Production of 1st validation batch in eco friendly bags with satisfying result
- Regulatory file for new production site and packaging submitted to Notified body (Approval expected in Q1)
- Recruitment of PrimECC project team completed

### **Ongoing**

- Awaiting final approval from Notified body and Ethical committee
- Preparation for start of clinical documentation trial
  - » Multicenter trial at 7 Swedish hospitals planned to start in Q1, conditioned of administrative approvals



## Outlook - Focus areas

### Thoracic Transplantation / Surgery (Primary focus)

- » Lungs Further support development of EVLP technology and clinical practice
- » Heart Start and running of multicenter studies for regulatory approval on all major markets
- » PrimECC® Strat and running of 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
- » Future investigation of how to employ XVIVO technology into abdominal organs

### Long-term goals

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



