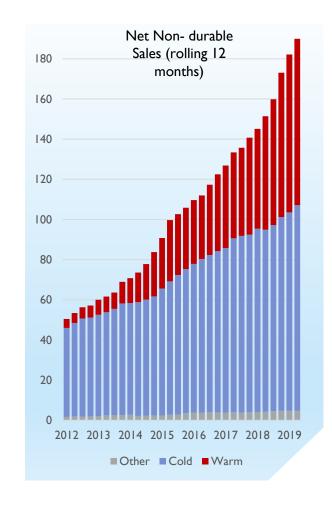


Highlights 2019

- PMA from the FDA (USA) for the products XPS[™] and STEEN Solution[™]
- 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
- Approval from the Swedish MPA to begin clinical studies for heart preservation products
- High interest from to the world's leading heart transplant surgeons after XVIVO Perfusion's heart preservation machine was showed
- PrimECC production validation batch in eco friendly bag done

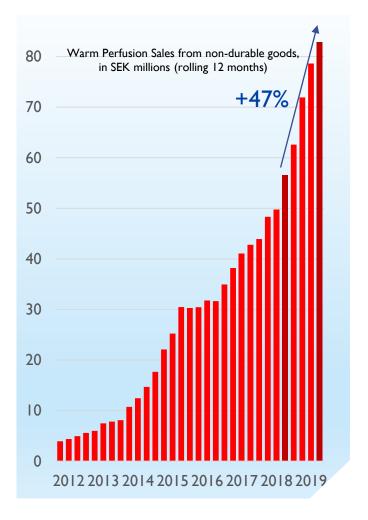


Sales highlights 2019

- Continued strong sales of non-durable goods:
 - » Non-durable sales +20% in Q2 and +21% in HY1
- Warm non-durable growth rolling 12 month + 47% (YoY)

Continuation of positive sales trend for Cold preservation

Canada new country with XPS in Q2





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	2018
(SEK Millions)	Jan-Jun	Jan-Jun	Full year
Net sales	104.1	88.6	187.9
Net sales non-Durable goods	97.3	80.1	172.7
Gross profit	78.6	63.1	136.0
Gross Margin %	75%	71%	72%
Gross Margin non-Durable goods %	77%	77%	77%
Selling expenses %	-27%	-25%	-26%
Admin. expenses %	-11%	-10%	-12%
R&D exp. excl. Amort. ** %	-20%	-19%	-20%
Items effecting comparability * %	-9%	-3%	0%
R&D Amortization ** %	-7%	-6%	-6%
Other expenses excl. Items effecting comp. * %	-1%	-1%	-2%
Operating Result %	0%	8%	7%
Operating Result * %	0%	0%	7%
EBITDA excl. items effecting comperability	20.8	18.0	30.9
EBITDA excl. items effecting comperability %	20%	20%	16%
EBITDA	11.3	15.2	30.9
EBITDA %	11%	17%	16%

Items effecting comparability are **9.5 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: 9.5 (2.8) MSEK.

**R&D Amortization: 7.2 (5.4) MSEK.



PMA approval from the FDA

- XVIVO received FDA approval (PMA) for XPS[™] and STEEN Solution[™]
- 10 year effort including 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



PMA approval from the FDA

- The PMA approval simplifies the reimbursement process for US clinics.
- With the PMA approval restrictions that the HDE had are lifted, hence more EVLP can be performed.
- Increased interest from UT after PMA approval and continued good collaboration

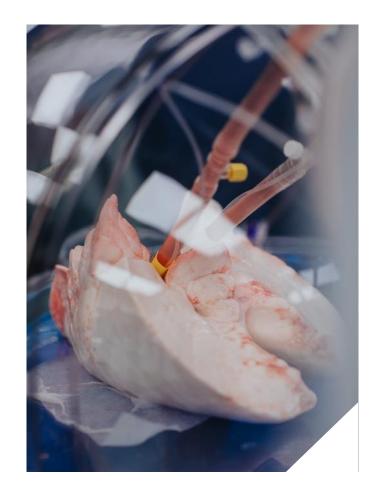




XVIVO enable future growth within lung transplantation

XVIVO will continue to clinically develop EVLP:

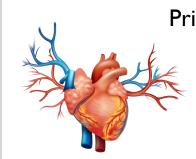
- Continued development of the XPS[™] to enable online parameters for better decision making.
 - » New weight sensor
 - » Updated software with smart sequencing
 - » CO2, Glucose, and Lactate sensors
- Expanded use of DCD* lungs for transplantation
- Ex vivo infection therapy e.g. Pneumonia therapy and virus reduction
- EVLP protocol development
- Investigate immunological response during EVLP targeting short term organ function & long term survival







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™

^{*}Isolated Tissue Therapy

XVIVO - Heart transplantation

Development stage: Early Clinical Phase

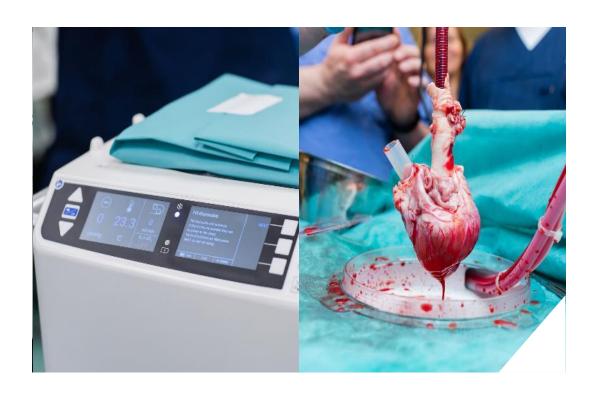
Heart perfusion and preservation solution and device developed by Prof. Steen

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 (first in the world)

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

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





^{*}Non ischemic heart preservation

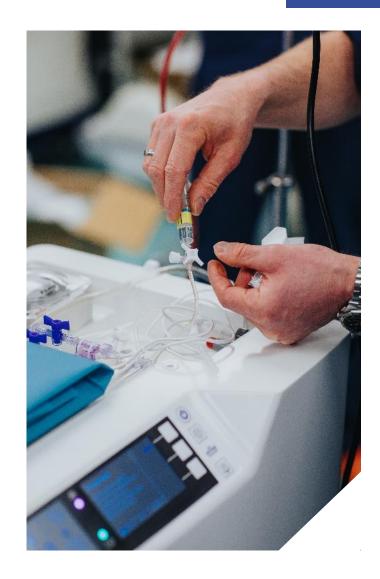
XVIVO - Heart transplantation

Jan-Jun 2019 Accomplishments

- » Patents for the heart preservation fluid approved in the US and Europe
- » Pre-clinical and technical testing successfully performed
- » XVIVO Perfusion's heart preservation machine demonstrated with high interest from leading heart transplant surgeons worldwide
- Received regulatory approval from the Swedish MPA for clinical studies in heart preservation

Next steps

- » Production ramp up of machine, disposable and solution
- » Start of multicenter clinical trial in Europe
- » Preparation for multicenter clinical study in the US and Australia





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.

<u>Accomplishments</u>

- 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

 Production of 1st validation batch in eco friendly bags with satisfying result



- Regulatory clearance for new production site and packaging
- 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



