

REPORT ON OPERATIONS 2016

TELEPHONE CONFERENCE

FEBRUARY 8, 2017

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO



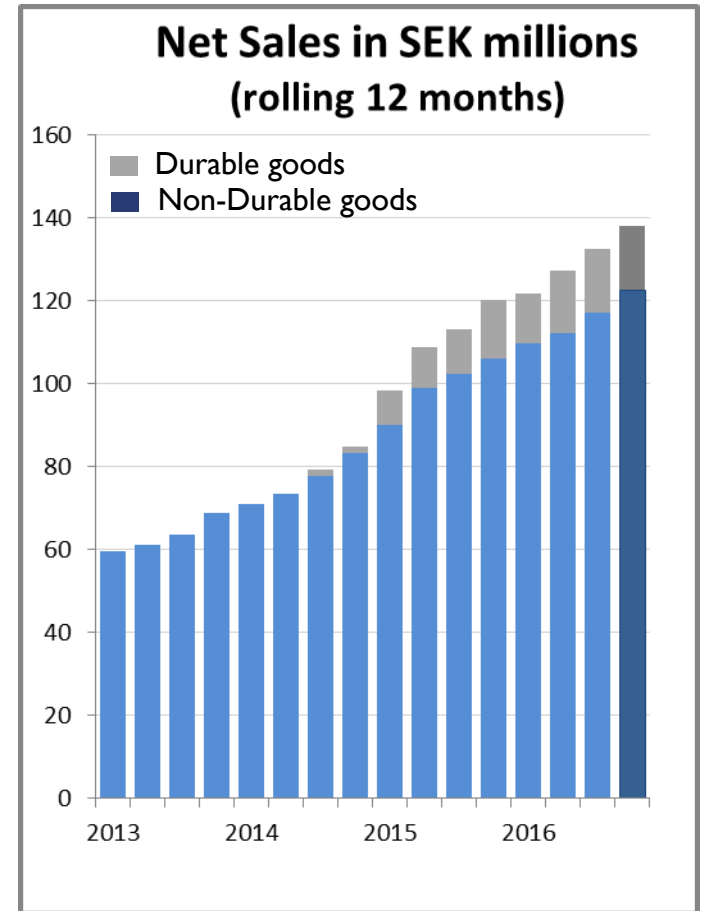
HIGHLIGHTS 2016

- **Sales 138 MSEK with growth +15%**
 - 10 XPS™/LS™ delivered

- **EBITDA excl. IEC* 26 MSEK (21) = 19% (17%)**

- **Integration of Vivoline complete – LS™ & DLS™ now sold by XVIVO’s M&S team**

- **Strengthen R&D portfolio:**
 - Heart transplant project acquired
 - Liver transplant clinical study – good initial results
 - Clinical STEEN Solution cancer study started
 - PrimECC clinical study started (CE-marked & patented)

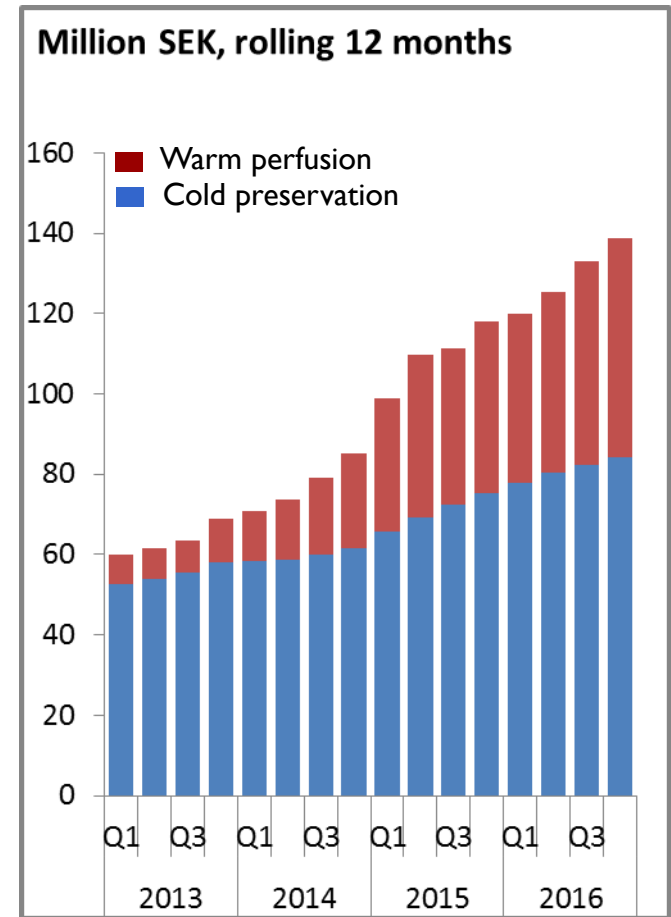


*EBITDA excl. IEC = EBITDA excluding items effecting comparability

HIGHLIGHTS Q4

- Q4 sales +18%, 38 MSEK
- 43% warm perfusion of Q4 sales
- Cold preservation sales enhanced by more EVLP
- Successful integration & enhancement of EU sales team
- Cleanroom production facility upgrade
- R&D capabilities enhanced
 - Dev. Team additions
 - Igelösa collaboration
 - Dev. Lab upgrade

Net sales



PROFIT & LOSS

		Jan – Dec	Jan – Dec
	(SEK millions)	2016	2015
Sales +15%	Net sales	138.2	120.2
	Net sales non-Durable goods	122.5	106.0
Gross profit +20%	Gross profit	102.2	85.0
	Gross Margin %	74%	71%
	Gross Margin non-Durable goods %	80%	78%
R&D investment new indications	Selling expenses excl. items eff. comp%	-24%	-27%
	Admin. expenses excl. items eff. comp%*	-12%	-10%
Vivoline / Nasdaq	R&D exp. excl. Amort. & items eff. comp%*	-19%	-16%
	Items effecting comparability*	-8%	-2%
	R&D Amortization %*	-7%	-8%
	Other income/expenses %	-2%	-1%
	Operating Result %	2%	6%
EBITDA +27%	EBITDA excl. items eff. comp.*	26.4	20.8
excl. items effecting comp.	EBITDA excl. items eff. comp%	19%	17%
	EBITDA	16.0	18.8
	EBITDA %	12%	16%

* Items effecting comparability: 2016 10.4 (2.0) MSEK. R&D Amortization : 2016 10.4 (10.2) MSEK.

IMPROVED OPERATING CASH-FLOW 2016

Cash flow 2016 in MSEK

Improved Operating cash flow in 2016

*~12 MSEK invest in R&D proj &
~8 MSEK invest in mtrl. fixed assets*

Cash impact fr Vivoline acquisition / Nasdaq -19 MSEK

Cash beginning of 2016	41
Oper. cash flow excl items eff. Comp.*	+22
Investments (fixed assets)	-20
Other items (currency, warrant prgm)	+1
Cash effect of Vivoline acq. / Nasdaq*	-19
Cash end of 2016	25

* Cash impact from Vivoline acquisition and items eff. comp. is 1) cash component in purchase price minus cash in Vivoline on June 30, 2016., which equals 9.5 MSEK., and 2) Cash effect of cost items effecting comparability, which equals 9.5 MSEK.

VIVOLINE INTEGRATION

- Sales:
 - M&S team fully integrated
 - H2 Sales from Vivoline 4.3 MSEK
 - 2 LS™ sold in Q4

- R&D:
 - Intensified the Heart transplant research project with Prof. Steen
 - Enhanced development competence and facility

- Costs:

Cost synergies fully captured

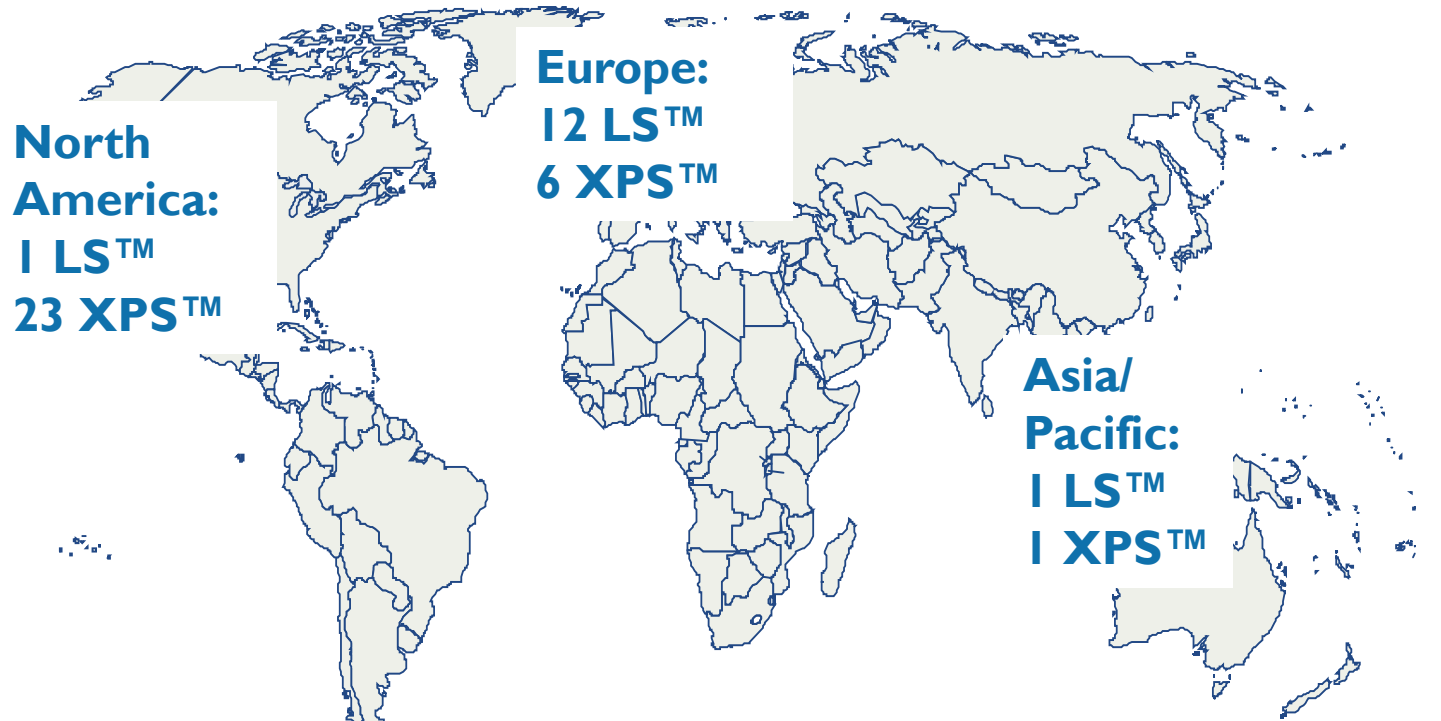
- Production:

Production move to Lund ongoing, synergies estimated from Q3, 2017

Igelösa – Prof. Steen’s research institute



PRODUCT AND MARKET EVLP-MACHINE FOOTPRINT: 44 XPS™ AND LS™



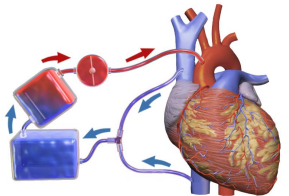
R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO



Expansion of Lung transplantation indication, EVLP improvement projects



Heart Transplant project in late pre-clinical phase (est. clinical phase 2017)



PrimECC improve clinical proof, late clinical phase



Drug administration to isolated organs (e.g. Cancer) with STEEN Solution™, early clinical phase



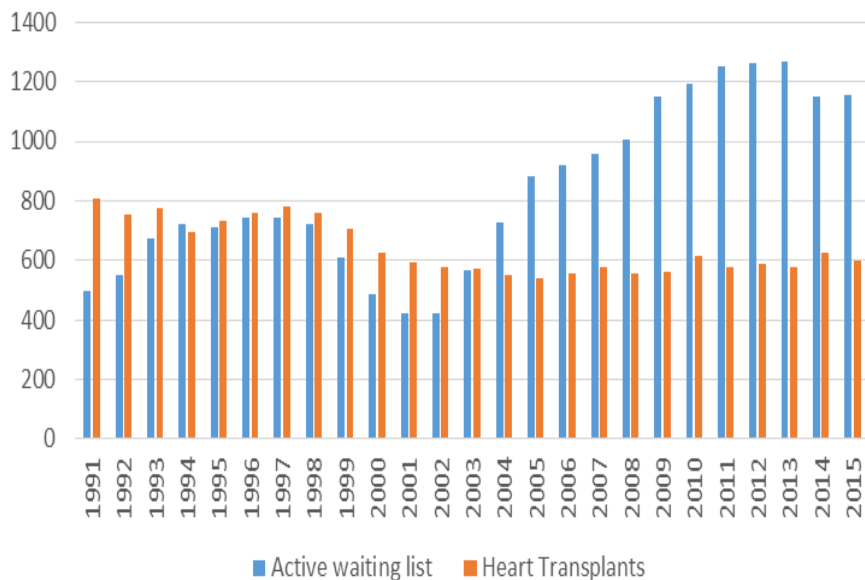
STEEN Solution™ for Liver Transplant, early clinical phase



R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

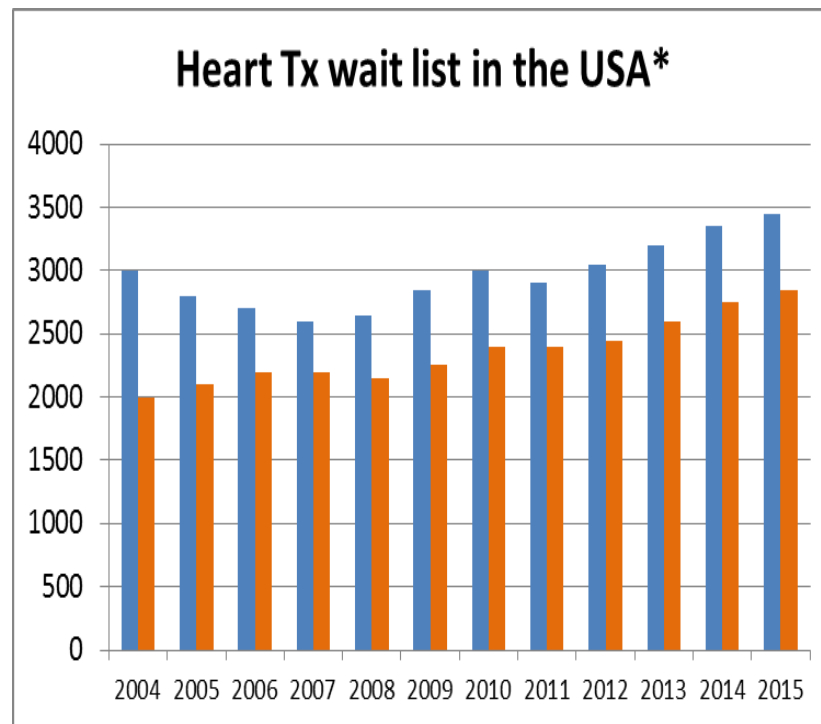
HEART TX AND WAIT LIST PART OF EU & USA

Heart waiting list and transplants*



*Eurotransplant - Austria, Belgium, Croatia, Germany, Hungary, Netherlands, Slovenia, Luxembourg

Heart Tx wait list in the USA*



*OPTN/SRTR 2015 Annual Data Report



R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

HEART TRANSPLANTATION (HEART TX)

	Heart Tx	Lung Tx
No. of procedures/year	~6 500	~5 000
Annual Tx growth	+4%	+6%
No. of clinics (EU + USA)	~230 (Overlap 25%)	~130
No. of organs used	~25%	~20%
Wait list mortality/removal	~25%	~25%
Max accepted ischemic time	4-6h	10-12h
Five year survival post Tx	~70%	~50%

HEART TRANSPLANTATION DEMAND



Heart transplantation market has high potential:

- **7-10 million people die every year in heart related illnesses**
- **Important limiting factor today: max 4-6 hours outside body possible**
- **Age of donor correlated with susceptibility of ischemic time
= older donor's hearts frequently not used**
- **Good outcome make heart transplant an attractive therapy**





R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

XVIVO'S HEART TRANSPLANTATION PROJECT

XVIVO's new heart perfusion and preservation solution and device developed by Prof. Steen:

- Pre-clinical proof of concept studies indicate:
 - Longer preservation time possible
 - Better organ quality

- Next development stage:
 - Proof of concept/safety study on 6 patients planned to start Q1/Q2 2017

Heart Tx very good fit with XVIVO's existing Lung Tx business:

- Synergies in development, regulatory & marketing
- XVIVO experienced in similar project



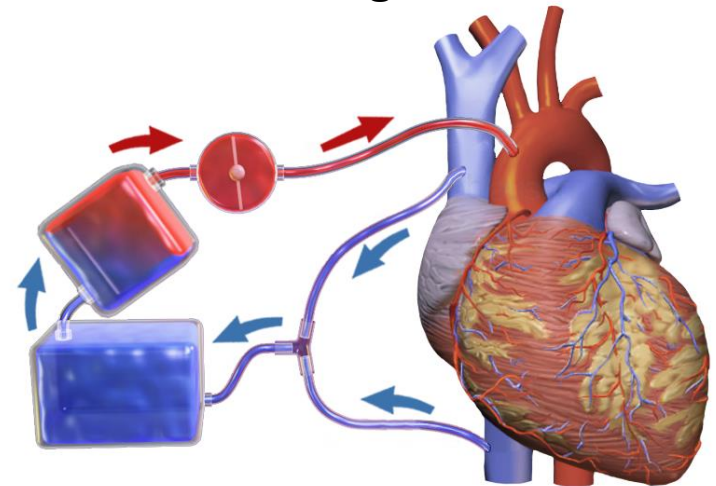
R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

- PRIMECC®

□ Clinical study on 80 patients started in Q2, 2016. Results Q4, 2017

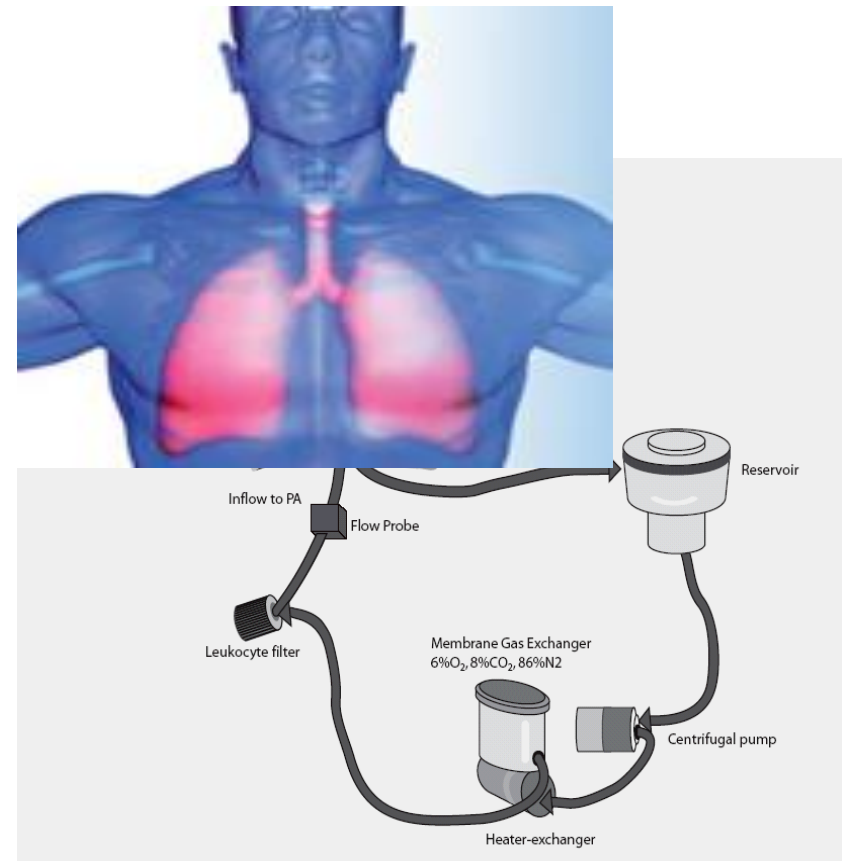
- PRIMECC® developed to avoid side-effects when priming heart-lung machines.
 - >300 000 open heart surgeries every year in the USA alone.
- Previous clinical “proof of concept” study showed interesting results.
- Patent granted in EU, USA and China.
- CE marked Class III Medical Device.

Schematic drawing of heart with heart-lung machine



R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO - ISOLATED TISSUE THERAPY

- **Proof of concept study perfusing lungs in vivo (IVLP) is ongoing.**
- **Problem today with many therapies:**
 - **Severe side effects on non-targeted organs.**
 - **Lack of good method to administer drugs to isolated organs or tissues.**
- **STEEN Solution™ has the potential to be used as a drug delivery method for isolated tissues.**



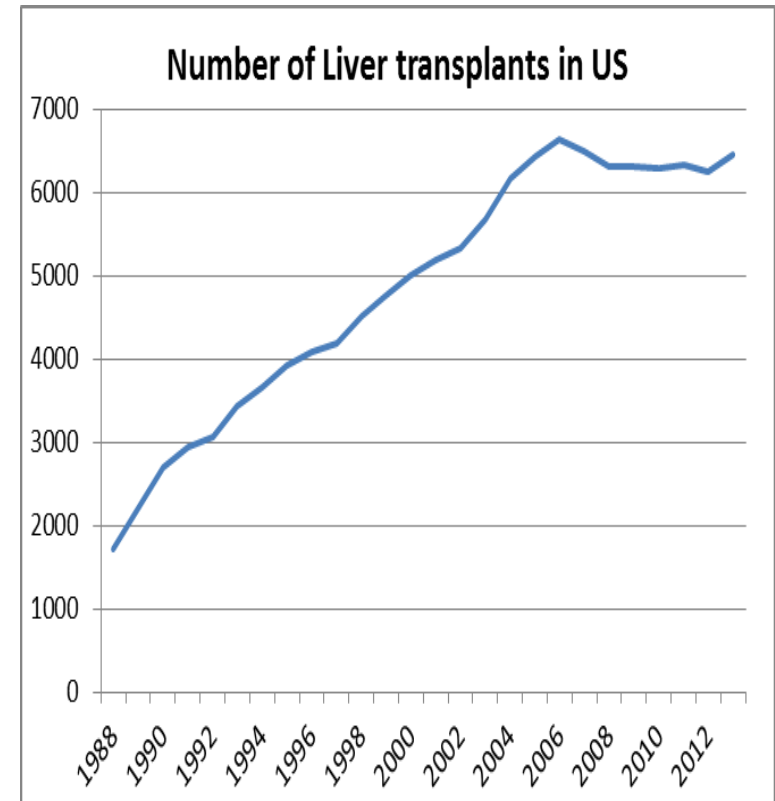
R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

- LIVER PERFUSION

- Proof of concept study ongoing where Liver is perfused with STEEN Solution™ before transplantation

- Liver transplantation market has high potential:
 - Waiting list mortality high >20%
 - Liver transplant indication x5 compared to lungs

- First results from liver clinical study published with good clinical results



OUTLOOK 2017

Lung Transplantation

- Continue to capture synergies from the Vivoline acquisition:
 - Sales synergies: 44 clinics with access to EVLP machines*
 - Capture production synergies
 - Enhanced XVIVO R&D capacity with upgraded facility in Lund
 - Close collaboration with Prof. Steen's Igelösa research Institute

R&D - New indications

- Focus on accelerating Heart transplant project, clinical phase planned for 2017
- On-going Clinical studies:
 - PrimECC for open heart surgery
 - Isolated tissue therapy (Cancer / STEEN Solution™ IVLP**)
 - Liver transplantation STEEN Solution™

* EVLP machines are XPS™ and LS™ both used with STEEN Solution

** IVLP or In Vivo Lung Perfusion is when a lung is perfused inside the body.

THANK YOU!