

# REPORT ON OPERATIONS 2015

TELEPHONE CONFERENCE

FEBRUARY 4, 2016

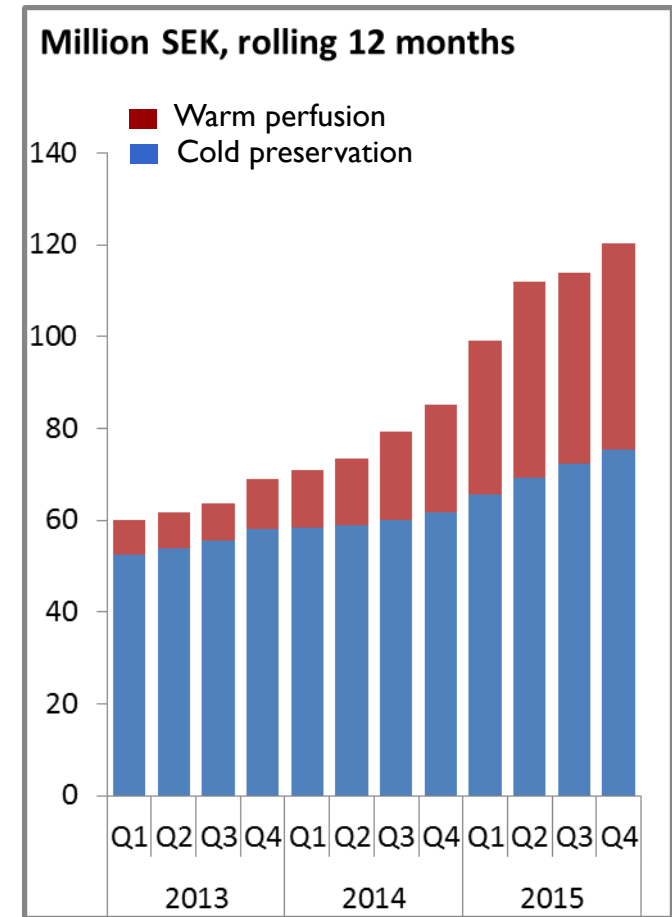
MAGNUS NILSSON, CEO  
CHRISTOFFER ROSENBLAD, CFO



# HIGHLIGHTS 2015

- ❑ Sales 120 MSEK and Growth +42%
- ❑ EBITDA 16% (12%)
- ❑ First liver transplant with STEEN Solution™
- ❑ First XPS™ delivered to Europe
- ❑ Organizational focus on the US:
  - +4 headcount in M&S and R&D
  - EVLP training facility

## Net sales



# HIGHLIGHTS Q4, 2015

- ❑ Sales 33 MSEK with growth +28%
- ❑ EBITDA 21% (Q12%)
- ❑ 3 XPS™ delivered, whereof one to Vienna, Austria (worlds 2nd largest LTx clinic)
- ❑ STEEN Solution™ approved in:
  - China
  - Russia



# PREPARATIONS FOR NASDAQ LISTING

- Report on Operations 2015 in accordance with IFRS**
  - No amortization of R&D Goodwill**
  
- Application for listing on First North Premier**
  
- Preparations for Nasdaq main market listing ongoing with aim of listing during 2016**

# PROFIT & LOSS

		January - December		October - December	
(SEK millions)		2015	2014	2015	2014
<b>Sales growth 42% in 2015</b>	<b>Net sales</b>	120.2	84.7	32.7	25.5
	<b>Net sales non-Durable goods</b>	106.0	83.2	29.1	25.5
<b>High gross margin</b>	<b>Gross Margin %</b>	71%	76%	75%	77%
	<b>Gross Margin non-Durable goods %</b>	78%	77%	80%	77%
<b>Economies of scale in Admin and R&amp;D</b>	Selling expenses %	-27%	-27%	-28%	-23%
	Administrative expenses %	-11%	-13%	-10%	-12%
	R&D expenses excl. Amort & Legal %*	-16%	-18%	-16%	-20%
	R&D expenses % Legal one-time*	-1%	-5%	0%	-11%
	R&D Amortization %*	-8%	-4%	-8%	-10%
	Other expenses %	-1%	0%	-1%	+1%
	Operating Result %	6%	9%	12%	2%
<b>Good profit level simultaneously with higher investments in Marketing and R&amp;D.</b>	<b>EBITDA</b>	18.8	11.4	6.9	3.1
	<b>EBITDA %</b>	16%	13%	21%	12%
	<i>EBITDA excl. one-time cost*</i>	20.8	15.7	7.2	5.9

\* One-time costs Jan-Dec 2015 were SEK 2.0 (4.3) million. Amortization on the US STEEN Solution asset Jan-Dec 2015 was SEK 9.8 (3.3) million.

# USA: HIGH INTEREST FOR XPS™

- ❑ **7 new XPS™ contracts in 2015 to Texas, Illinois, Florida x2, California, Ohio, Virginia (new states with XPS™)**
- ❑ **Warm perfusion\* products incl. the XPS™ grew +170% in 2015**
- ❑ **Expert User accredited training program set up and fully booked**
- ❑ **New US M&S director and additional +2 Customer tech. support in 2016**



\* Warm perfusion products are products used for EVLP e.g. STEEN Solution™, XPS™ and XPS™ single-use products.

# EUROPE: INCREASING INTEREST FOR XPS™

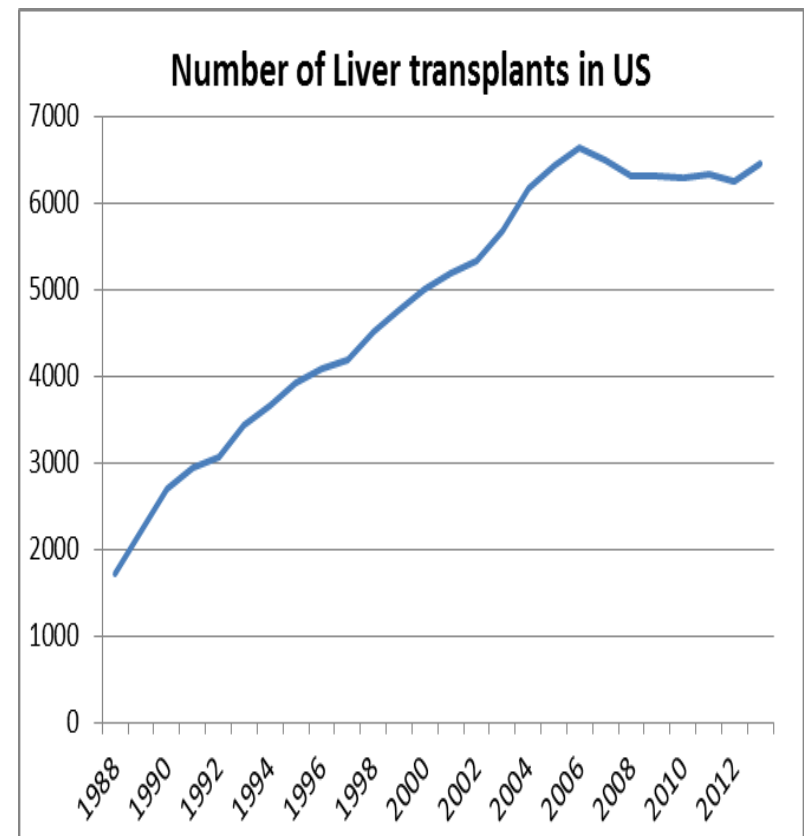
- ❑ 4 XPS™ delivered in 2015
- ❑ XPS™ delivered to Vienna - the worlds 2<sup>nd</sup> largest clinic.
- ❑ 1 XPS™ contract signed after the end of the quarter (Lausanne)
- ❑ New EMEA M&S Sales director
- ❑ Continued high interest from clinics to setup EVLP with XPS™



# R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

## - LIVER PERFUSION

- **Proof of concept study ongoing:**
  - **11 patients transplanted with a Liver perfused with STEEN Solution™ with good clinical outcome**
  
- **Liver transplantation market has high potential:**
  - **Waiting list mortality high >20%**
  - **Liver transplant indication x5 compared to lungs.**

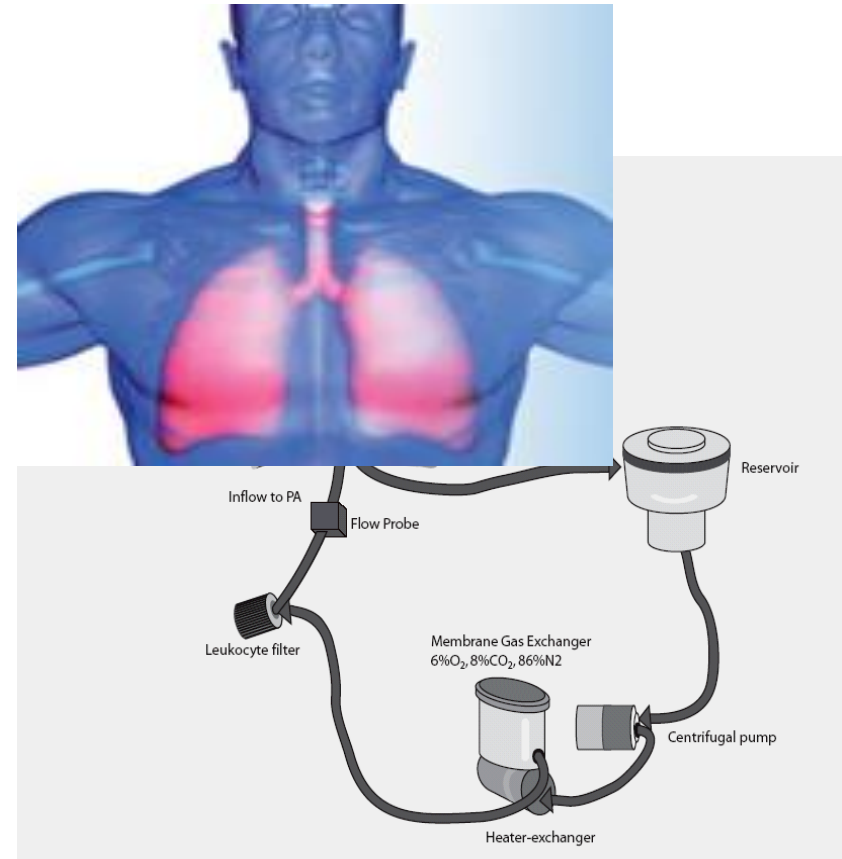




# R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

## - ISOLATED TISSUE THERAPY

- Problem today:
  - 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.
  
- Proof of concept study planned to start in Q1 2016

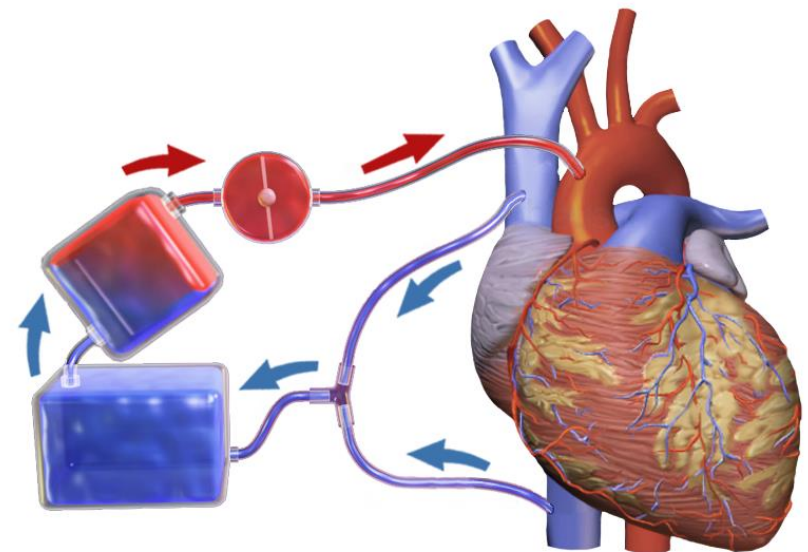


# R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

## - PRIMECC®

- ❑ Patent-protected product in major markets
- ❑ CE-marked product
- ❑ PrimECC® developed to avoid side-effects when priming heart-lung machines
- ❑ Heart-lung machines used in open heart surgery
- ❑ Clinical study on 80 patients planned to start in Q1, 2016

### Schematic drawing of heart with heart-lung machine



# OUTLOOK 2016

- ❑ **Increase number of clinics with XPS™**
  - **Continued high interest in the US and Europe to acquire XPS™**
- ❑ **Increase usage of XPS™ - support and train clinics**
  - **Support clinics with training & re-training programs and workshops**
  - **Support with paperwork and reimbursement**
  - **Larger M&S team to support clinics on site during EVLP**
- ❑ **Support Liver STEEN Solution™ research to prove safety of STEEN Solution™ in Liver transplantation**
- ❑ **Plan to enter clinical phase for Cancer STEEN Solution™ IVLP\* in Q1, 2016**
- ❑ **Clinical study PrimECC during 2016**

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

# LONG TERM FOCUS (3 Y)

## Broaden use of STEEN Solution™ technology

- ❑ Warm perfusion with STEEN Solution™ for lung transplantation as a standard treatment (gold standard).
- ❑ Clinical development of STEEN Solution™ for Liver transplantation.
- ❑ Enter clinical development of Isolated tissue therapy with STEEN Solution™.
- ❑ Continued pre-clinical research of warm perfusion with STEEN Solution™ for other organs.

THANK YOU!