

INTERIM REPORT JAN-SEP 2016

TELEPHONE CONFERENCE

OCTOBER 27, 2016

MAGNUS NILSSON, CEO
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HIGHLIGHTS Q3, 2016

- ❑ Sales 32 MSEK with growth +19%
- ❑ Operating cash-flow 5.4 MSEK (2.8)
and EBITDA excl. IEC* 5.4 MSEK (4.4)
- ❑ Integration of Vivoline:
 - M&S – Fully integrated in Q3 (Vivoline Sales 1.6 MSEK in Q3 and first LS sold in October)
 - R&D – intensified the Heart transplant research project with Prof. Steen
 - Admin – Fully integrated in Q3



*EBITDA IEC = EBITDA excluding items effecting comparability

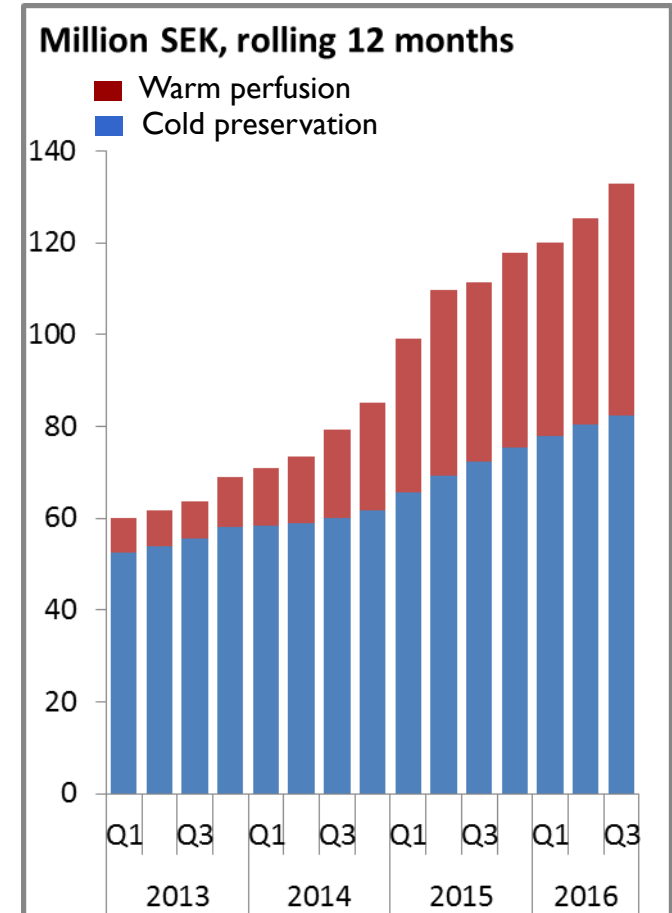
SALES

- ❑ Q3 sales +19%
- ❑ 35% of sales in Q3 from warm perfusion, Cold preservation sales enhanced by more Warm perfusion activity

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- ❑ Jan-Sep sales +14%
 - ❑ 6 XPS™ sold in 2016 Jan-Sep:
 - 4 in the US and 2 in Europe
 - France and Switzerland new countries

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- ❑ 2 LS™ contracts to Spain in Oct.

Net sales



PROFIT & LOSS

(SEK millions)		January – September		January – December
		2016	2015	2015
Sales grew +14%	Net sales	99.8	87.6	120.2
	Net sales non-Durable goods	88.0	76.8	106.0
Gross Margin grew +22%	Gross Margin %	74%	69%	71%
	Gross Margin non-Durable goods %	80%	77%	78%
Items effecting comp. increased	Selling expenses items eff. comp%	-24%	-26%	-27%
	Admin. expenses excl. items eff. comp%*	-12%	-11%	-10%
	R&D exp. excl. Amort. & items eff. comp%*	-18%	-16%	-16%
	Items effecting comparability*	-7%	-2%	-2%
	R&D Amortization %*	-8%	-9%	-8%
	Other income/expenses %	-2%	-1%	-1%
	Operating Result %	3%	4%	6%
EBITDA excl. items effecting comp. grew +45%	EBITDA excl. items eff. comp.*	19.7	13.6	20.8
	EBITDA excl. items eff. comp%	20%	15%	17%
	EBITDA	12.4	11.9	18.8
	EBITDA %	12%	14%	16%

* Items effecting comparability: Jan-Sep 2016 SEK 7.3 (1.7) million. Jan-Dec 2015 SEK 2.0 million.
R&D Amortization : Jan-Sep 2016 SEK 7.7 (7.6) million. Jan-Dec 2015 SEK 10.2 million.

CASH FLOW

Stable cash position in Jan-Sep 2016 due to improved operating cash-flow, even with Vivoline acquisition.

Estimated remaining integration and listing costs are 6 MSEK

		January - September		January - December
		2016	2015	2015
<i>Improved Operating cash flow</i>	(SEK millions)			
	Operating cash flow	18.7	5.7	8.6
	Cash flow from other investing activities	-12.6	-10.1	-14.3
	Cash flow from financing activities	0.3	-1.5	-1.5
<i>Cash impact from Vivoline acquisition -7.8 MSEK</i>	Cash impact from Vivoline acquisition*	-7.8	-	-
	Cash-flow for the period	-1.4	-5.9	-7.2
	Cash at the beginning of the period	41.2	48.2	48.2
	Exchange rate difference in liquid funds	0.2	0.3	0.2
<i>Cash -1.1 MSEK vs. Dec 31, 2015.</i>	Cash at the end of the period	40.1	42.6	41.2

* Cash impact from Vivoline acquisition is cash component in purchase price minus cash in Vivoline on June 30, 2016.

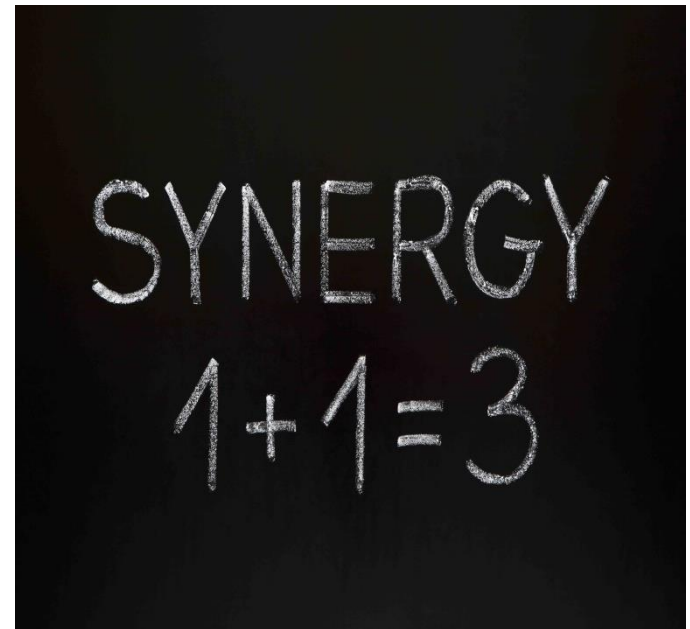
VIVOLINE INTEGRATION - SYNERGIES

- **Sales:**
 - M&S team fully integrated
 - Q3 Sales from Vivoline 1.6 MSEK
 - 2 LS™ sold in Q4

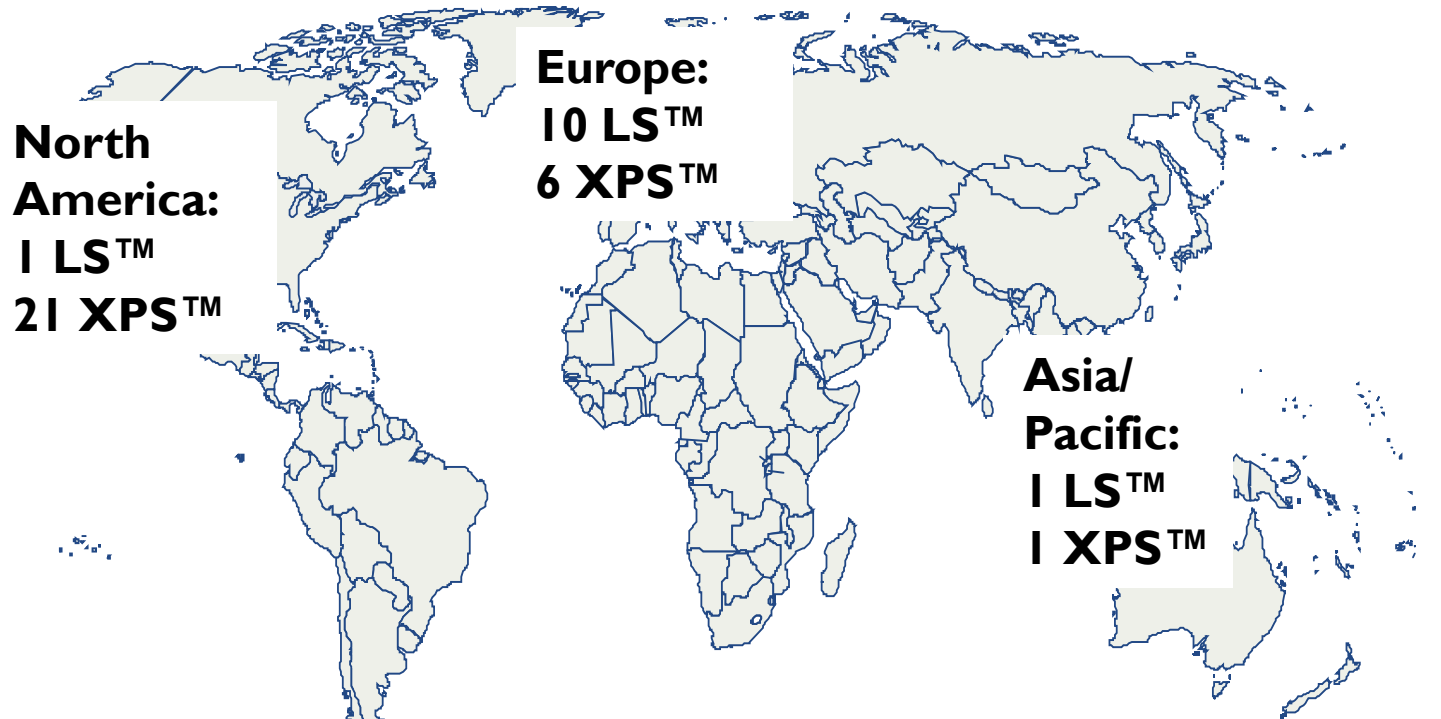
- **R&D:**
Intensified the Heart transplant research project with Prof. Steen

- **Costs:**
Cost synergies to be fully captured as of Q4, 2016

- **Production:**
Production move to Lund ongoing, synergies estimated from Q3, 2017



PRODUCT AND MARKET EVLP-MACHINE FOOTPRINT: 40 XPS™ AND LS™



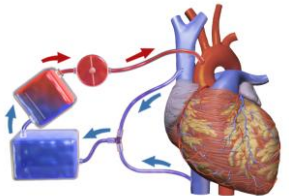
R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO



Expansion of Lung transplantation indication, EVLP improvement projects



Heart Transplant project in late pre-clinical phase (est. clinical phase Q4 2016 / Q1 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

- LUNG PERFUSION

- MAKING MORE DONOR LUNGS AVAILABLE USING EVLP

- **Research supported:**
 - **where lungs from donors with virus infection is cleansed from virus during EVLP**
 - **where lungs from donors with bacterial infection is treated with antibiotic during EVLP**
 - **where lungs from uncontrolled DCD (“circulatory death” donor died before organs tested) are used after EVLP**

R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

HEART TRANSPLANTATION

Heart transplantation market has high potential:

- 7-10 million people die every year in heart related illnesses
- Heart Tx waiting list mortality high >20%
- Only ~25% of donated hearts are transplanted
- Important limiting factor today: max 4-5 hours outside body possible



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

- Pre-clinical studies indicate longer preservation time possible
- Next development stage:
 - Proof of concept/safety study on 6 patients planned to start Q4 2016 / Q1 2017

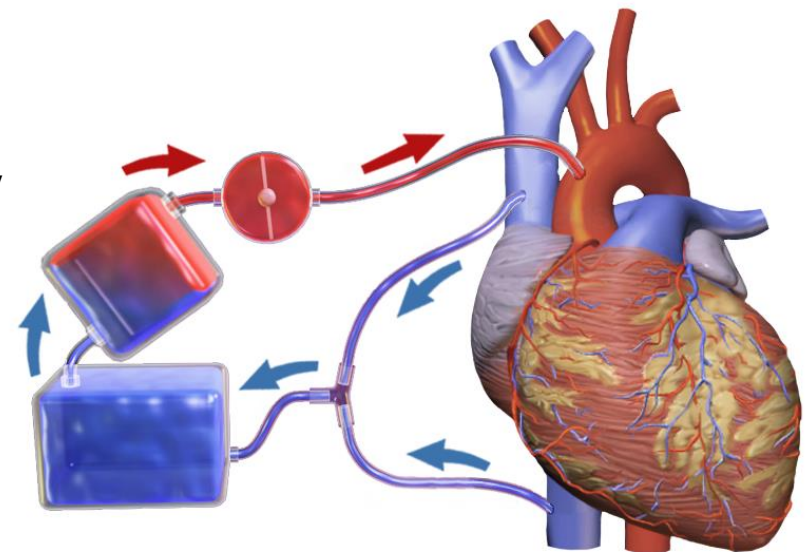


R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

- PRIMECC®

- ❑ Patent granted in EU, USA and China.
- ❑ CE marked Class III Medical Device.
- ❑ PRIMECC® developed to avoid side-effects when priming heart-lung machines.
 - >300 000 open heart surgeries every year in the USA alone.
- ❑ Clinical “proof of concept” study showed interesting results.
- ❑ Clinical study on 80 patients started in Q2, 2016.

Schematic drawing of heart with heart-lung machine

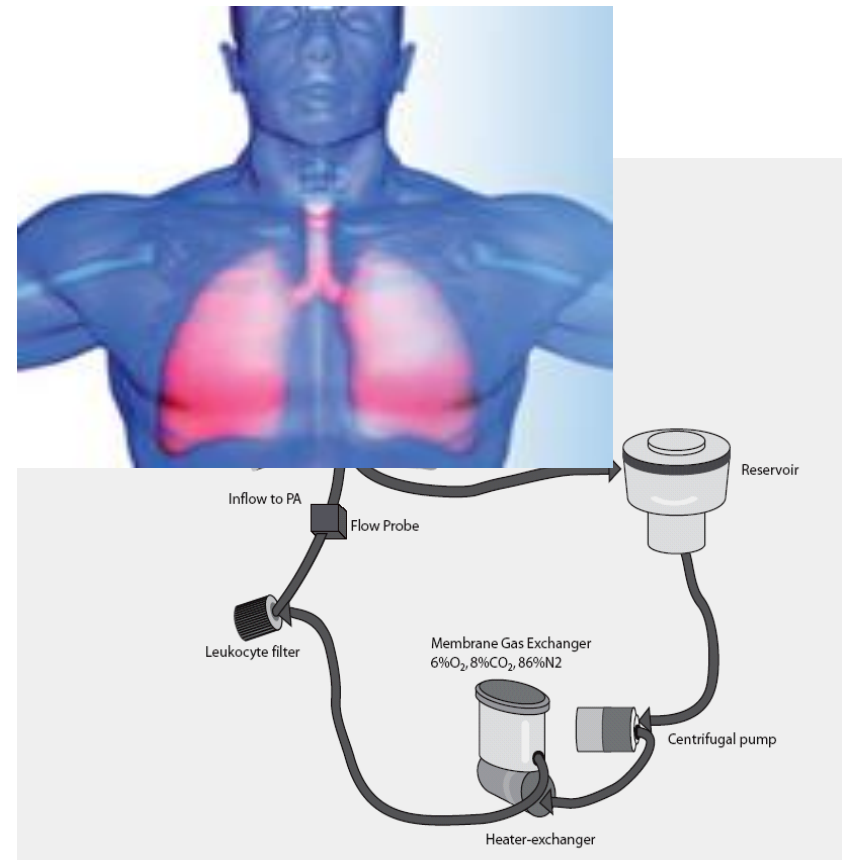


R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO - ISOLATED TISSUE THERAPY

- 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.**

- **Proof of concept study perfusing lungs in vivo (IVLP) is ongoing.**

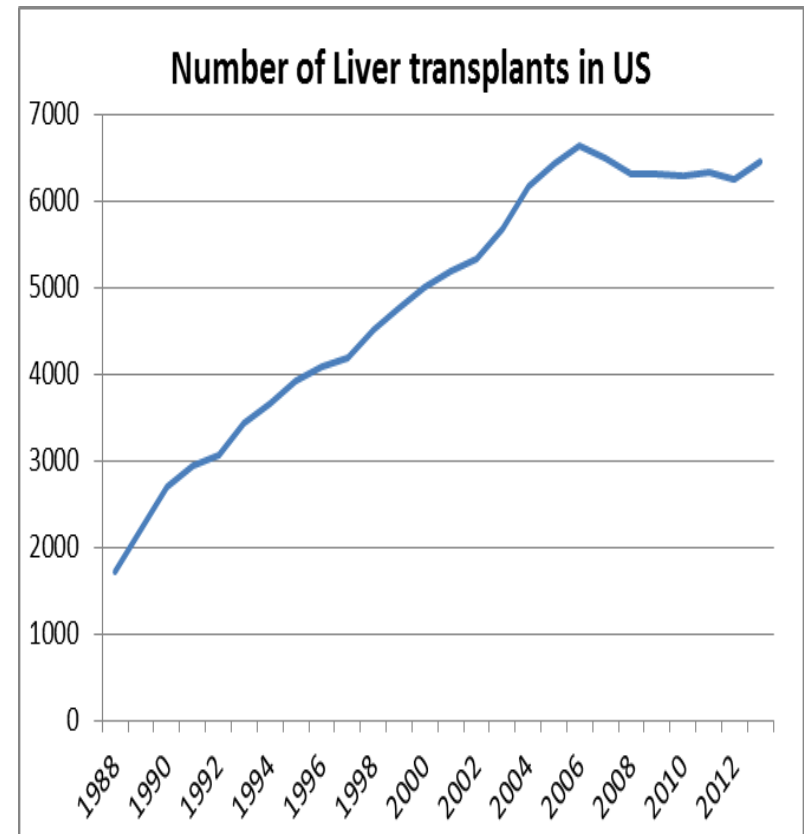


R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

- LIVER PERFUSION

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

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



OUTLOOK 2016/17

Lung Transplantation

- ❑ Continued Integration of Vivoline:
 - Capture sales synergies: 40 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

New indications

- ❑ Accelerate Heart transplant project, clinical phase planned q4-16/q1-17
- ❑ 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!