

# INTERIM REPORT JAN-MAR 2016

TELEPHONE CONFERENCE

APRIL 26, 2016

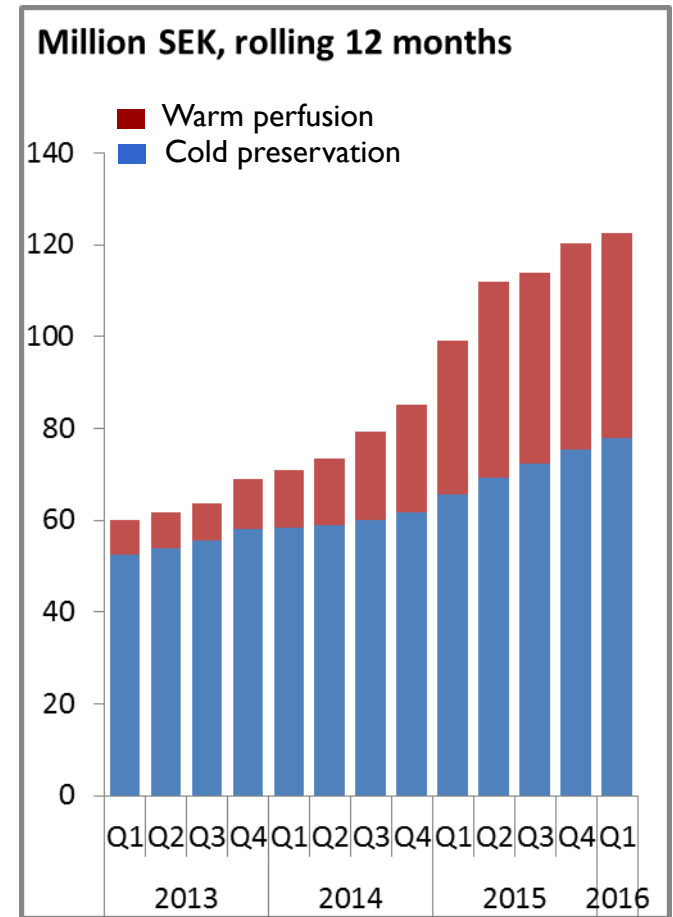
MAGNUS NILSSON, CEO  
CHRISTOFFER ROSENBLAD, CFO



# HIGHLIGHTS Q1, 2016

- ❑ Record sales of 34 MSEK
- ❑ Sales non-durable goods 29 MSEK and Growth +17% in local currency
- ❑ EBITDA excl. one-time costs 22% (14%)
- ❑ Operating cash-flow 5.3 (-5.9) MSEK
- ❑ PRIMECC® CE marked
- ❑ 14<sup>th</sup> consecutive quarter with growth and positive EBITDA i.e. all quarters since listing in October 2012.

## Net sales



# PROFIT & LOSS

	(SEK millions)	January - March		January - December
		2016	2015	2015
<i>Sales excl. durable goods grew +16%</i>	<b>Net sales</b>	<b>33.5</b>	<b>31.8</b>	<b>120.2</b>
	<b>Net sales non-Durable goods</b>	<b>29.1</b>	<b>25.1</b>	<b>106.0</b>
	<b>Gross Margin %</b>	<b>72%</b>	<b>61%</b>	<b>71%</b>
<i>Gross Margin grew +24%</i>	<b>Gross Margin non-Durable goods %</b>	<b>80%</b>	<b>76%</b>	<b>78%</b>
	Selling expenses %	-22%	-23%	-27%
<i>Continued high investments in M&amp;S and R&amp;D</i>	Admin. expenses excl. one-time costs %*	-12%	-10%	-10%
	R&D exp. excl. Amort. & one-time costs %*	-16%	-13%	-16%
	One-time costs*	-7%	-5%	-2%
	R&D Amortization %*	-8%	-8%	-8%
	Other income/expenses %	-2%	-1%	-1%
	Operating Result %	5%	1%	6%
<i>EBITDA excl. one-time costs grew +61%</i>	<b>EBITDA</b>	<b>4.9</b>	<b>2.9</b>	<b>18.8</b>
	<b>EBITDA %</b>	<b>15%</b>	<b>9%</b>	<b>16%</b>
	<b>EBITDA excl. one-time costs*</b>	<b>7.3</b>	<b>4.5</b>	<b>20.8</b>
	<b>EBITDA excl. one-time costs %*</b>	<b>22%</b>	<b>14%</b>	<b>17%</b>

\* One-time costs: Jan-Mar 2016 SEK 2.4 (1.7) million. Jan-Dec 2015 SEK 2.0 million.  
 R&D Amortization : Jan-Mar 2016 SEK 2.6 (2.5) million. Jan-Dec 2015 SEK 10.2 million.

# CASH FLOW

Improved cash position in Q1 2016 mainly from improved operating cash flow.

Improved Operating cash flow mainly from improved EBITDA margin

(SEK millions)		January - March		January - December
		2016	2015	2015
<i>Improved Operating cash flow</i>	Operating cash flow	5.3	-5.9	8.6
	Cash flow from investing activities	-3.6	-3.0	-14.3
	Cash flow from financing activities	0	0	-1.5
Cash-flow for the period		1.7	-8.9	-7.2
<i>Cash improved +3.0 MSEK vs. one year ago.</i>	Cash at the beginning of the period	41.2	48.2	48.2
	Exchange rate difference in liquid funds	-0.2	0.4	0.2
	Cash at the end of the period	42.7	39.7	41.2

# USA: CONTINUED HIGH INTEREST FOR XPS™

- ❑ 18 clinics with access to XPS™
  
- ❑ Key focus is training of clinics:
  - Expert User accredited training program fully booked
  
- ❑ Strengthen US team:
  - 12 HC in Q1 2016 vs. 5 HC in Q1 2015.
  - New US M&S director
  - 4 Customer tech. and clinical support



# EUROPE: BREAKTHROUGH FOR XPS™

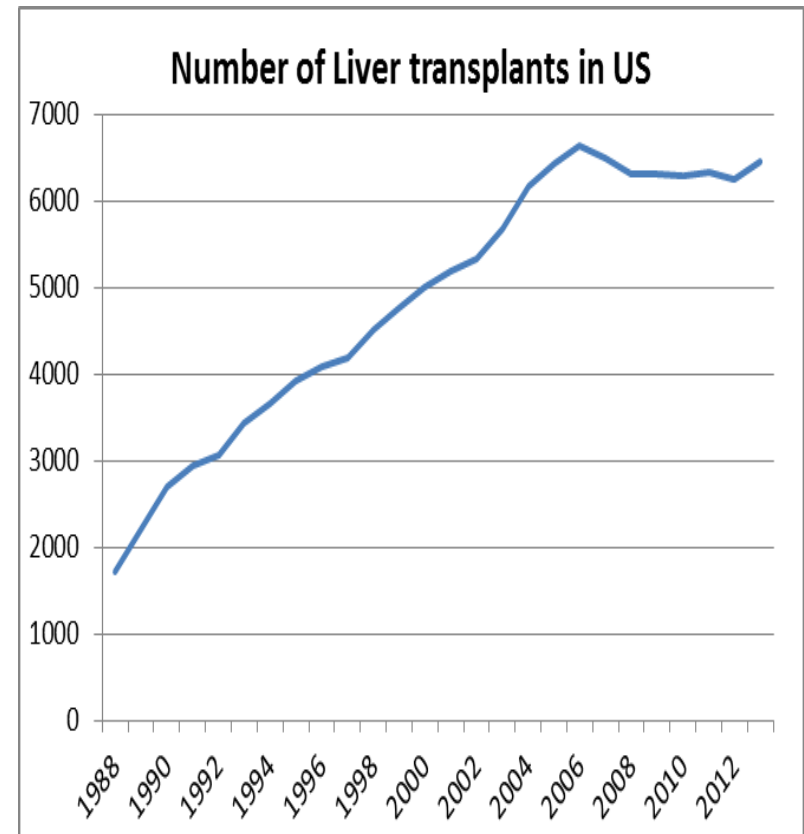
- ❑ 6 clinics with access to XPS™
- ❑ 2 new XPS™ contracts in Q1 to new countries (France and Switzerland) and 4 new XPS in the past 4 months
- ❑ Implemented key learnings from the US in EU e.g. training and clinical support
- ❑ New EMEA M&S Sales director
- ❑ Continued high interest from clinics to setup EVLP with XPS™



# R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

## - LIVER PERFUSION

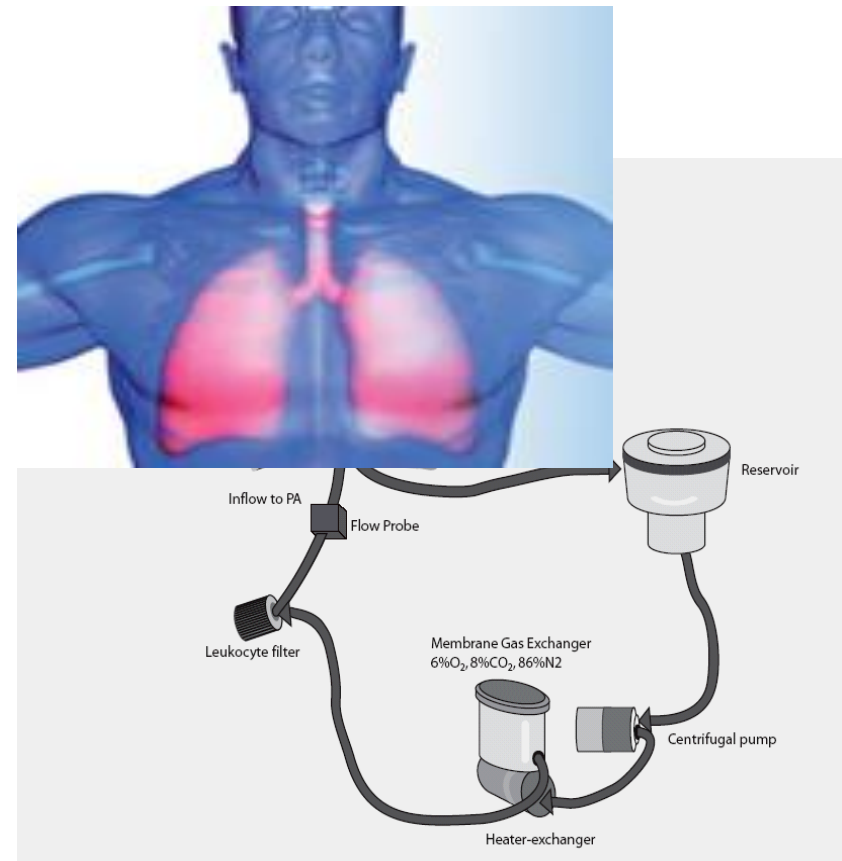
- **Proof of concept study ongoing:**
  - **13 patients transplanted with a Liver perfused with STEEN Solution™ with good clinical outcome**
  - **Initial results presented**
- **Liver transplantation market has high potential:**
  - **Waiting list mortality high >20%**
  - **Liver transplant indication 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 Q2 2016.



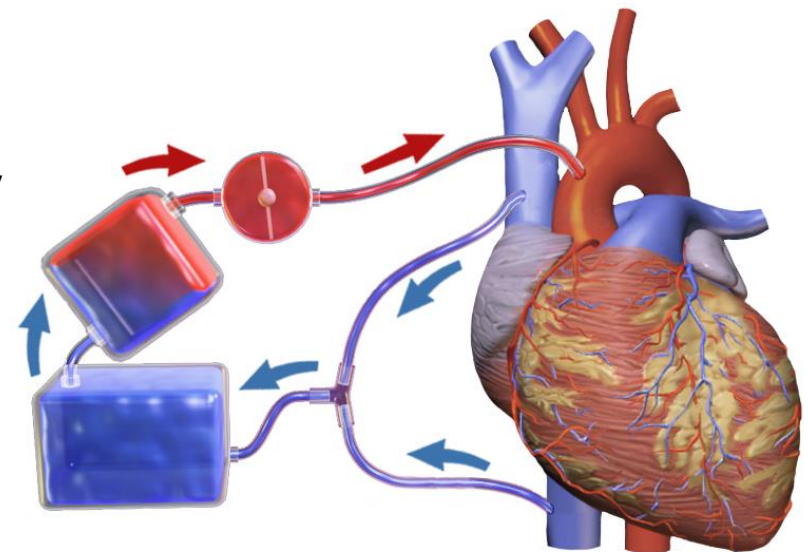


# R&D: BROADENING OF INDICATION & PRODUCT PORTFOLIO

## - 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 planned to start in Q2, 2016.

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



# VIVOLINE OFFER – SUMMARY

- Public recommended offer to holders of shares and warrants in Vivoline.
- Vivoline's 3 largest shareholders holding 48% of the shares have undertaken to accept the offer.
- Value of the Offer amounts to around SEK 128.5 million (based on XVIVO share price at the time of announcement).

# VIVOLINE OFFER – RATIONALE

## □ XVIVO and Vivoline is a perfect match:

- XVIVO has world wide experience of taking products from research project through approval and a successful market launch.
- Vivoline has through Prof. Steen collaboration research capabilities and own clean room production capabilities.

## □ The combined company will:

- Be in a good position to become the global leader in both lung and heart perfusion and preservation.
- Create more resources and competence to take Stig Steen's world-leading research to the global market.
- Own facility to develop and produce disposables

# OUTLOOK 2016

## Lung Transplantation:

- ❑ 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, reimbursement and workshops
  - Larger M&S team to support clinics on site during EVLP

## New indications:

- ❑ Liver STEEN Solution™ study to prove safety of STEEN Solution™ in Liver transplantation
- ❑ Enter Clinical study Cancer / STEEN Solution™ IVLP\*
- ❑ Enter Clinical study PrimeECC

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

THANK YOU!