

# INTERIM REPORT JANUARY – SEPTEMBER 2017 TELEPHONE CONFERENCE

“NO ONE SHOULD HAVE TO DIE  
WAITING FOR A NEW ORGAN”

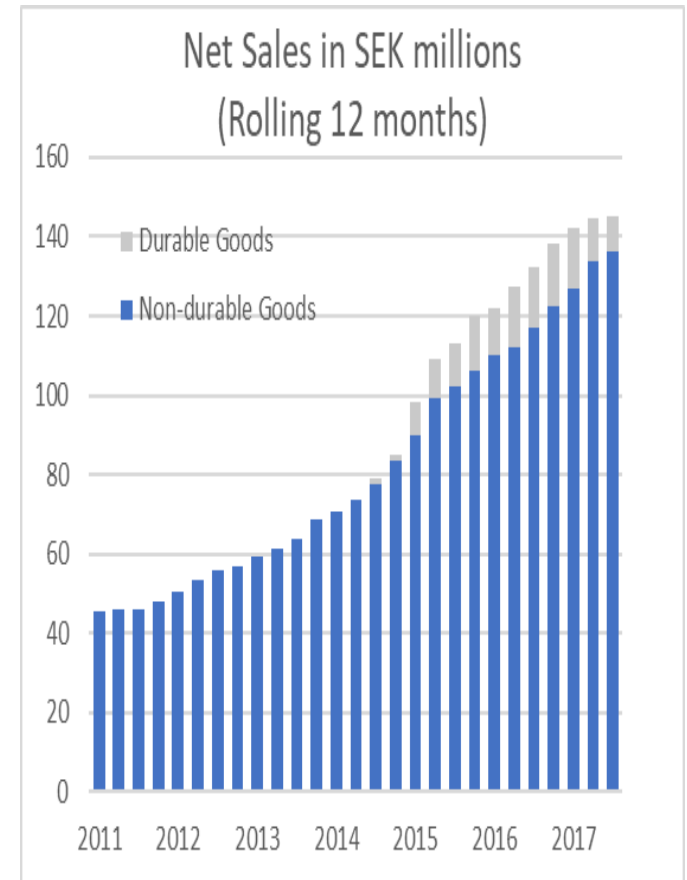
October 27, 2017

MAGNUS NILSSON, CEO  
CHRISTOFFER ROSENBLAD, CFO



# HIGHLIGHTS 2017-Q3

- **First patient Heart transplanted using the new machine and solution**
- **Inclusion of all 110+110 patients in NOVEL study completed**
  - **Basis for PMA application**
- **Inclusion of all 40+40 patients in PrimECC study completed**
- **20 patients included in Liver study with STEEN Solution on DBD livers**
- **Clean room in Lund increased production and R&D capability**

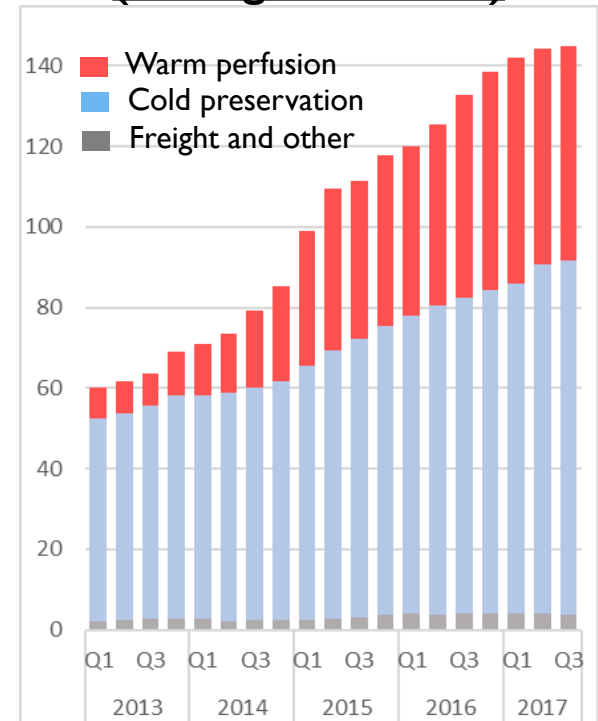


# SALES HIGHLIGHTS 2017 JAN - SEP

## DOUBLE DIGIT GROWTH FOR NON-DURABLE SALES

- **Sales:**
  - Non-durable goods +15%\* or 102 MSEK
- **EU & Aus: 2 new countries with XPS**
  - Australia & the Netherlands
  - Continued high interest from customers for the XPS & LS
- **USA - XPS contract signed with clinic in Kentucky and continued high interest from new clinics**

**Net sales in SEK millions**  
**(Rolling 12 months)**



\* Local currency growth for non-durable goods +13% YTD and +11% Q3

# PROFIT & LOSS

		Jan – Sep		Jan – Dec
(SEK millions)		2017	2016	2016
	Net sales	106.7	99.8	138.2
<b>Sales non-durable +15%</b>	<b>Net sales non-Durable goods</b>	<b>101.6</b>	<b>88.0</b>	<b>122.5</b>
	Gross profit	81.6	73.3	102.2
<b>Continued strong gross margin</b>	<b>Gross Margin %</b>	<b>76%</b>	<b>74%</b>	<b>74%</b>
	<b>Gross Margin non-Durable goods %</b>	<b>79%</b>	<b>80%</b>	<b>80%</b>
<b>Customer support build up</b>	Selling expenses excl. items aff. comp%	-31%	-24%	-24%
	Admin. expenses excl. items aff. comp%*	-13%	-12%	-12%
	R&D exp. excl. Amort. & items aff. comp%*	-19%	-18%	-19%
	Items affecting comparability*	-2%	-7%	-8%
	R&D Amortization %*	-7%	-8%	-7%
	Other income/expenses %	-2%	-2%	-2%
	Operating Result %	2%	3%	2%
<b>Running business profitable despite high investments in Marketing and R&amp;D</b>	<b>EBITDA excl. items eff. comp.*</b>	<b>15.7</b>	<b>19.7</b>	<b>26.4</b>
	<b>EBITDA excl. items eff. comp%</b>	<b>15%</b>	<b>20%</b>	<b>19%</b>
	<b>EBITDA</b>	<b>13.4</b>	<b>12.4</b>	<b>16.0</b>
	<b>EBITDA %</b>	<b>13%</b>	<b>12%</b>	<b>12%</b>

\* Items affecting comparability: 2017 Jan-Sep 2.3 (7.3) MSEK. R&D Amortization : 2017 Jan-Sep 7.9 (7.7) MSEK.

# PRODUCTS & MARKETS FOR FUTURE GROWTH

# XVIVO - FUTURE GROWTH OPPORTUNITIES



**Expansion of Lung transplantation indication, e.g. Infection (e.g. Hep C) EVLP treatment, Increase of DCD lungs**



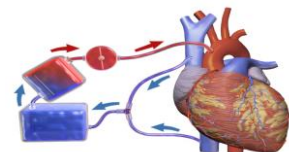
**Heart Transplant project, early clinical phase**



**STEEN Solution™ for Liver Transplant, clinical phase**



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



**PrimECC improve clinical proof, clinical phase**

\* ITT or Isolated Tissue Therapy is a therapy where one part of the body is isolated for treatment in order to avoid side effects.

# LUNG TRANSPLANTATION

XPS & STEEN Solution only FDA (HDE) approved device for warm perfusion of lungs



## **NOVEL study inclusion finalized:**

- **110 + 110 patients**
  - Follow-up 1 year
  - Form basis for **PMA** application, study documentation & monitoring and analysis ongoing
  - Dialogue with **FDA** ongoing
- **PAS (Post Approval Study)**
  - 5 patients until inclusion complete
  - Follow-up 3 years
- **Restrictions on patients and recipients will be removed when PAS inclusion finalized**



# LUNG TRANSPLANTATION

## Next steps for lung warm perfusion (EVLP)



**XVIVO will continue to clinically develop EVLP:**

- **DCD transplantation (Donation after Circulatory Death) – controlled / uncontrolled**
- **Infection therapy through EVLP, e.g. Pneumonia therapy and virus reduction – Hep C study: 2 patients included**
- **Investigate immunological response with EVLP targeting short- & long-term survival**
- **New markers and parameters for improved evaluation → safer decision making**



# XVIVO - HEART TRANSPLANTATION

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

---

- First clinical trial started with new technology:

- First patient transplanted with the new device (new solution and new machine)
  - Proof of concept study with 6 patients
- 

- Pre-clinical porcine proof of concept studies indicate:

- Avoidance of ischemic time → Better heart quality
  - Longer preservation time (24h) possible
  - Myocardium tests comparing perfused and non-perfused hearts.
- 

- Heart Tx very good fit with XVIVO

- XVIVO experience from Lung device development
- Synergies in development, regulatory and M&S
- Many of the same clinics and KOLs make Heart and Lung Tx

**Human hearts kept 'asleep' in a box  
can survive outside the body**

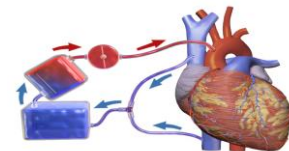
---



**Safe orthotopic transplantation of hearts  
harvested 24 hours after brain death and  
preserved for 24 hours**

Stig Steen, Audrius Paskevicius, Qiuming Liao & Trygve Sjöberg

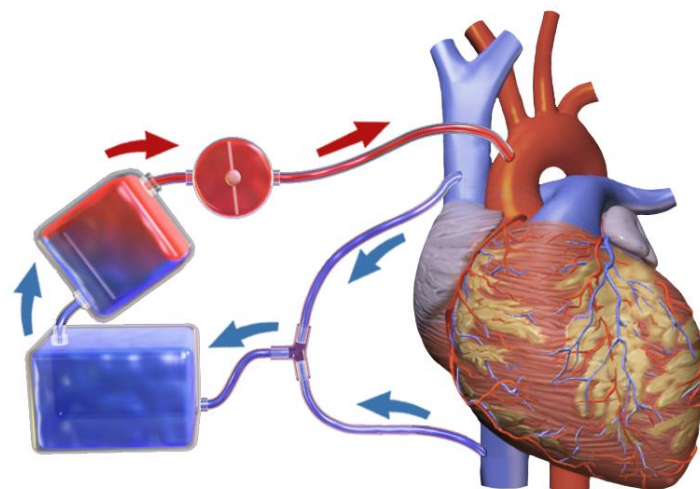
# PRIMECC



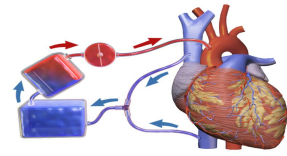
Tailor made priming solution aiming at improving patients' condition after having undergone open-heart surgery with a heart-lung machine

Schematic drawing of heart with heart-lung machine

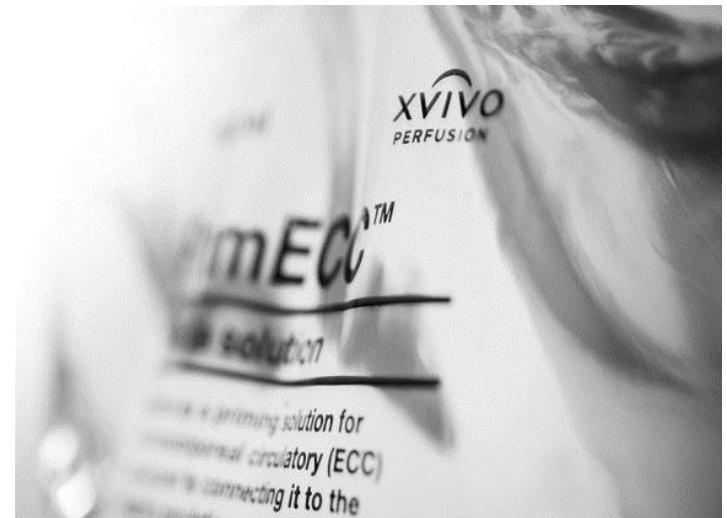
- **PRIMECC®** developed to avoid side-effects when priming heart-lung machines.
- **>300 000** open heart surgeries every year in the **USA** alone. Estimated **~1 million** in the world / year.
- **No FDA** approved product for indication.
- Previous performed clinical “proof of concept” study showed interesting results.
- Patent granted in **EU, USA** China and Japan.
- **CE** marked **Class III Medical Device**.



# PRIMECC STUDY INCLUSION FINALIZED



- **40 + 40 patients Sahlgrenska Univ. hosp.**
  - randomized, controlled, blinded
- **Aim to increase clinical documentation for PrimECC avoidance of side-effects**
- **Results estimated to be analyzed & published during Q4 2017 / Q1 2018**
- **EU & US multi-center studies planned to start after supporting clinical trial results are available**



# SUMMARY OTHER NEW INDICATIONS

- Liver transplantation:

- Results on 20 patients in first clinical STEEN Solution Liver study show good clinical results
- Marginal (DCD) Liver study planned to start in Canada on 2 centers



---

- Isolated Tissue Therapy - Cancer

- Proof of concept study perfusing lungs in vivo for treatment of cancer is ongoing
- 2nd patient successfully treated



# OUTLOOK Q4 2017 & 2018 - FOCUS AREAS

## Thoracic Surgery

- Lungs - Continue to increase footprint and use of EVLP technology
- Lungs - PMA application and submission
- Lungs - Reinforced clinical development of EVLP, especially in the US
- Heart - Accelerating Heart transplant clinical program
- PrimeECC - Analysis of PrimeECC clinical data and continued clinical program

## New indications

- Liver - STEEN Solution™ clinical development for DCD & marginal Livers
- ITT - Isolated tissue therapy (STEEN Solution™ IVLP: Cancer, Limb perfusion)
- Kidney – continued pre-clinical studies with STEEN Solution

# Strategic goals

- **Solidify position in Thoracic surgery - Lungs + Heart**
- **Build new business using STEEN Solution tech. in other indications**

# XVIVO PERFUSION

**Patients die waiting for an organ transplant**

**XVIVO has a Patented, Approved and Documented technology to make more organs available for the benefit of patients**

**XVIVO has the experience, capability, competence and technology to expand into more indications/markets**