# INTERIM REPORT JANUARY — JUNE 2017 TELEPHONE CONFERENCE

"NO ONE SHOULD HAVETO DIE WAITING FOR A NEW ORGAN"

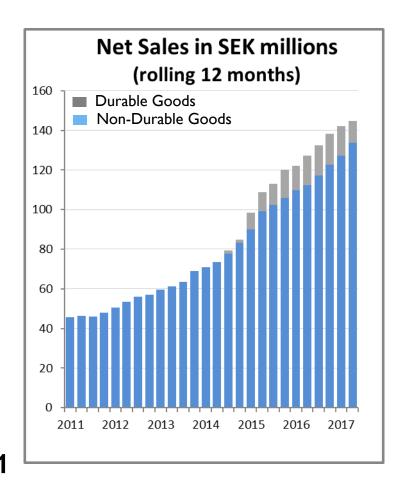
July 14, 2017

MAGNUS NILSSON, CEO CHRISTOFFER ROSENBLAD, CFO



# HIGHLIGHTS 2017-Q2

- Inclusion of all 110+110 patients in NOVEL study completed
  - Basis for PMA application
- Inclusion of all 40+40 patients in PrimECC study completed
- Directed issue of 181 MSEK
  - To faster develop Heart transplant portfolio
  - AP4, Norron, Swedbank & AP3 participated
- Rolling 12-months sales tripled since business spin off to own unit in Q4 2011





# SALES HIGHLIGHTS 2017 JAN - JUN DOUBLE DIGIT GROWTH FOR NON-DURABLE SALES

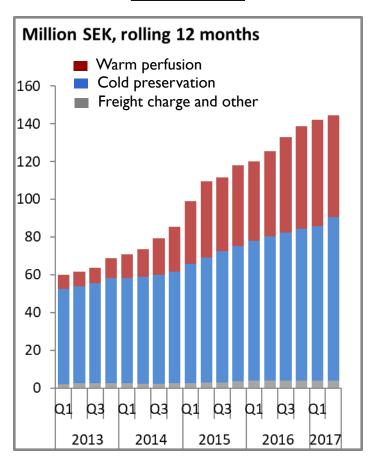
#### Sales:

- Non-durable goods +19%\* or 70 MSEK

- 2 new countries with XPS
  - Australia & the Netherlands
  - Continued high interest from customers for the XPS

 Q2 was 3<sup>rd</sup> consecutive quarter with warm non-durable sales on or above 11 MSEK

#### **Net sales**





<sup>\*</sup> Local currency growth +13% for non-durable goods.

# **PROFIT & LOSS**

Sales non-durable +19%

Continued strong gross margin

Customer support build up

Running business profitable despite high investments in Marketing and R&D

	Jan – Jun		Jan – Dec
(SEK millions)	2017	2016	2016
Net sales	74.5	68.0	138.2
Net sales non-Durable goods	70.0	58.8	122.5
Gross profit	56.3	49.1	102.2
Gross Margin %	76%	72%	74%
Gross Margin non-Durable goods %	79%	79%	80%
Selling expenses excl. items eff. comp%	-30%	-23%	-24%
Admin. expenses excl. items eff. comp%*	-13%	-11%	-12%
R&D exp. excl. Amort. & items eff. comp%*	-19%	-17%	-19%
Items effecting comparability*	-3%	-7%	-8%
R&D Amortization %*	-7%	-8%	-7%
Other income/expenses %	-2%	-2%	-2%
Operating Result %	3%	5%	2%
EBITDA excl. items eff. comp.*	11.3	14.2	26.4
EBITDA excl. items eff. comp%	15%	21%	19%
EBITDA	9.4	9.6	16.0
EBITDA %	13%	14%	12%

<sup>\*</sup> Items effecting comparability: 2017 Jan-Jun 1.9 (4.6) MSEK. R&D Amortization : 2017 Jan-Jun 5.3 (5.1) MSEK.

# PRODUCTS & MARKETS FOR FUTURE GROWTH



# XVIVO - FUTURE GROWTH OPPORTUNITIES



Expansion of Lung transplantation indication, EVLP improvement projects



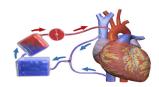
Heart Transplant project in late pre-clinical phase



STEEN Solution™ for Liver Transplant, early clinical phase



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



PrimECC improve clinical proof, late clinical phase



<sup>\*</sup> ITT or Isolated Tissue Therapy is a therapy where one part of he 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:

- II0 + II0 patients
  - follow-up I year
- Form basis for PMA application
  - study analysis through Q3/Q4
  - ongoing dialogue with FDA

#### PAS (Post Approval Study)

- -15 patients until 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)



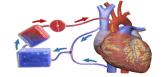
# **XVIVO** will continue to clinically develop **EVLP**:

- DCD transplantation (Donation after Circulatory Death)
  - controlled / uncontrolled
- Pediatric use of EVLP
- Ex Vivo Infection therapy through
   EVLP e.g. Pneumonia therapy and virus reduction
- Investigate immunological response with EVLP targeting long term survival





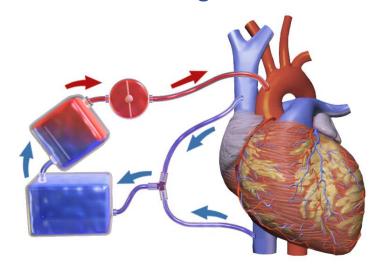
## PRIMECC



Tailor made priming solution aiming at improving patients' condition after having undergone open-heart surgery with a 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
     ~I million in the world per year.
- No FDA approved product for indication.
- Previous clinical "proof of concept" study showed interesting results.
- Patent granted in EU, USA China and Japan.
- CE marked Class III Medical Device.

# Schematic drawing of heart with heart-lung machine





# PRIMECC STUDY INCLUSION FINALIZED



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

- 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 before end of 2017
- US multi-center study planned when clinical results are available
- Launch planned when supporting clinical data are published





## SUMMARY OTHER NEW INDICATIONS

#### • Heart transplantation:

- Longer preservation time possible (24h in pigs)
- Proof of concept study ready to be started



#### Liver transplantation:

- First results from clinical study on standard criteria livers published with good clinical results
- Marginal (DCD) Liver study planned to start in Canada on 2 centers in 2017



#### Isolated Tissue Therapy - Cancer

 Proof of concept study perfusing lungs in vivo for treatment of cancer is ongoing.





## **OUTLOOK 2017 - FOCUS AREAS**

#### **Lung Transplantation**

- Continue to increase footprint and use of EVLP technology
- PMA application and submission
- Reinforced clinical development of EVLP, especially in the US
- Use clinical experience to further tailor technology for clinical usability

#### **R&D - New indications**

- Accelerating Heart transplant project
- Analysis of PrimECC clinical data
- Other on-going Clinical studies:
  - Liver transplantation STEEN Solution™
  - Isolated tissue therapy (Cancer / STEEN Solution™ IVLP)



### **XVIVO PERFUSION**

Patients die waiting for an organ transplant

XVIVO has a <u>Patented</u>, <u>Approved</u> and <u>Documented</u> 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

