

REPORT ON OPERATIONS 2017

TELEPHONE CONFERENCE

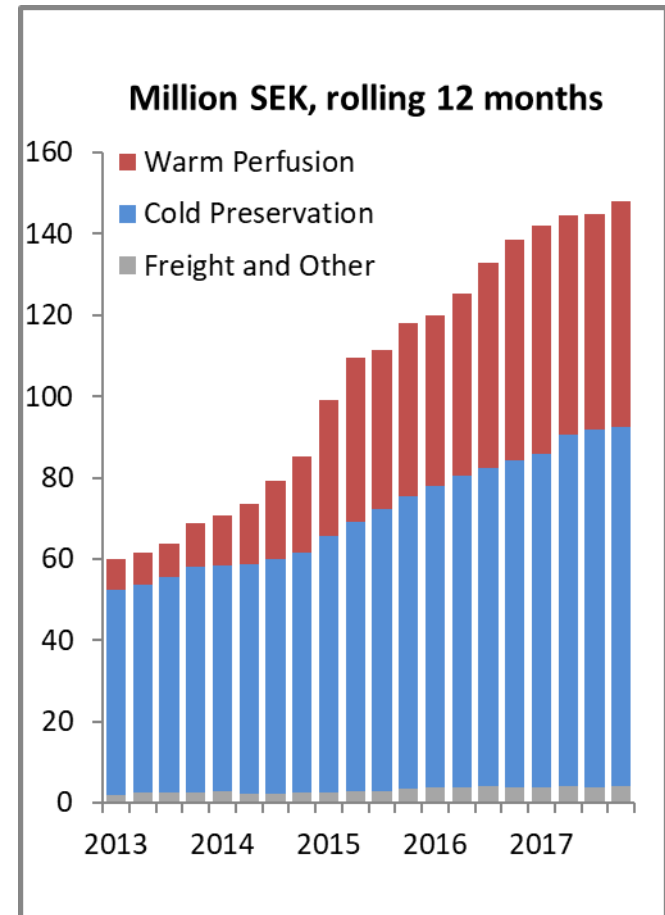
**“NO ONE SHOULD HAVE TO DIE
WAITING FOR A NEW ORGAN”**

February 12, 2018

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO

HIGHLIGHTS 2017-Q4

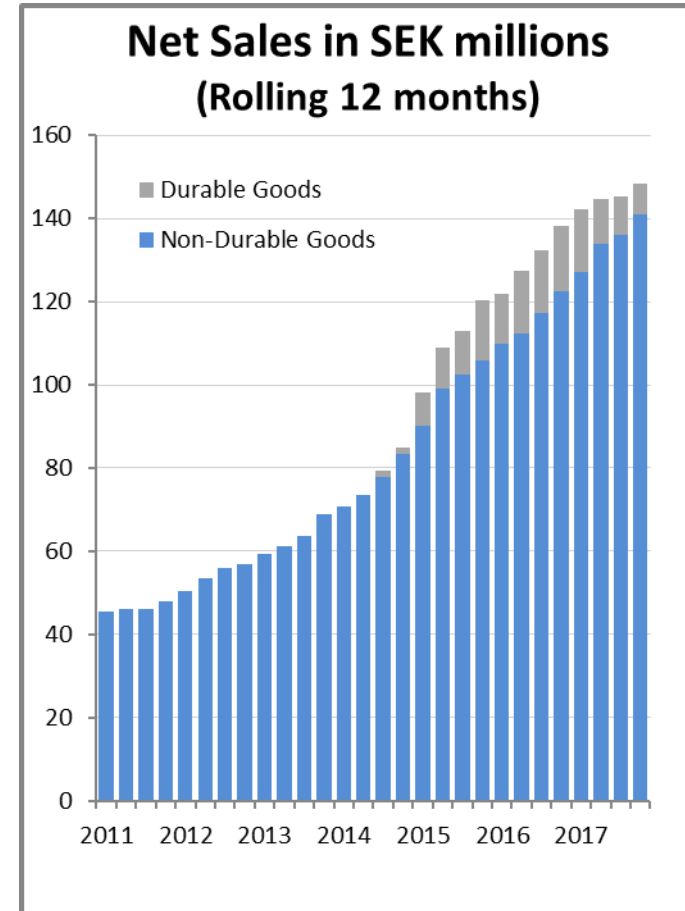
- **First XPS™ installed in China.**
- **Three XPS™ & LS™ delivered outside China.**
- **CPT Reimbursement codes obtained for doctor's time during EVLP procedure in US.**
- **Net Sales of non-durable goods increased by 21% in local currency to 39.4 MSEK*.**
- **Warm perfusion sales from non-durable goods accounted for 43% of total sales of non-durable goods.**



* Growth +15% for non-durable goods in SEK.

HIGHLIGHTS 2017

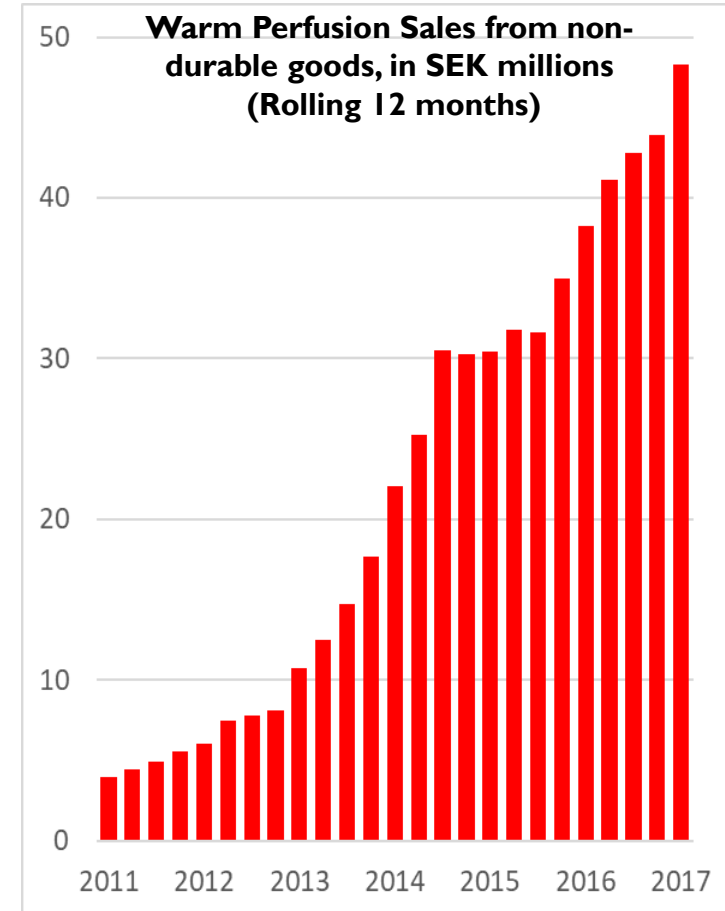
- **The first clinical heart transplant using the heart preservation technology developed by XVIVO's partner Professor Stig Steen was performed.**
- **All 220 patients included in the NOVEL study in the US which will form the basis of the company's PMA application.**
- **PrimECC study on 80 patients at Sahlgrenska University Hospital completed.**
- **A private placement of SEK 181 million was carried out to accelerate XVIVO's heart transplant project to the market.**



SALES HIGHLIGHTS 2017

DOUBLE DIGIT GROWTH FOR NON-DURABLE SALES

- **Sales:**
 - Non-durable goods increased by 15%* to 141 MSEK.
 - Net sales increased by 7% to 148 MSEK.
- **4 new countries with XPS™ or LS™**
 - Australia
 - China
 - Portugal
 - the Netherlands
- **EVLP reimbursement codes (CPT) obtained in the US.**



* Local currency growth +15% for non-durable goods.

SALES HIGHLIGHTS – CPT codes

- **A CPT* code is a way for a hospital and surgical team to get reimbursed for a specific procedure.**
- **The three new codes will simplify the reimbursement process for EVLP.**
- **The three new codes cover the full EVLP procedure:**
 - Code 1 - Related to preparation of marginal donor lungs.
 - Code 2 - Related to the EVLP process of a marginal lung.
 - Code 3 - Related to any additional hour(s) needed for an EVLP.



* CPT = Current Procedural Terminology

PROFIT & LOSS

*Sales non-durable
+15%*

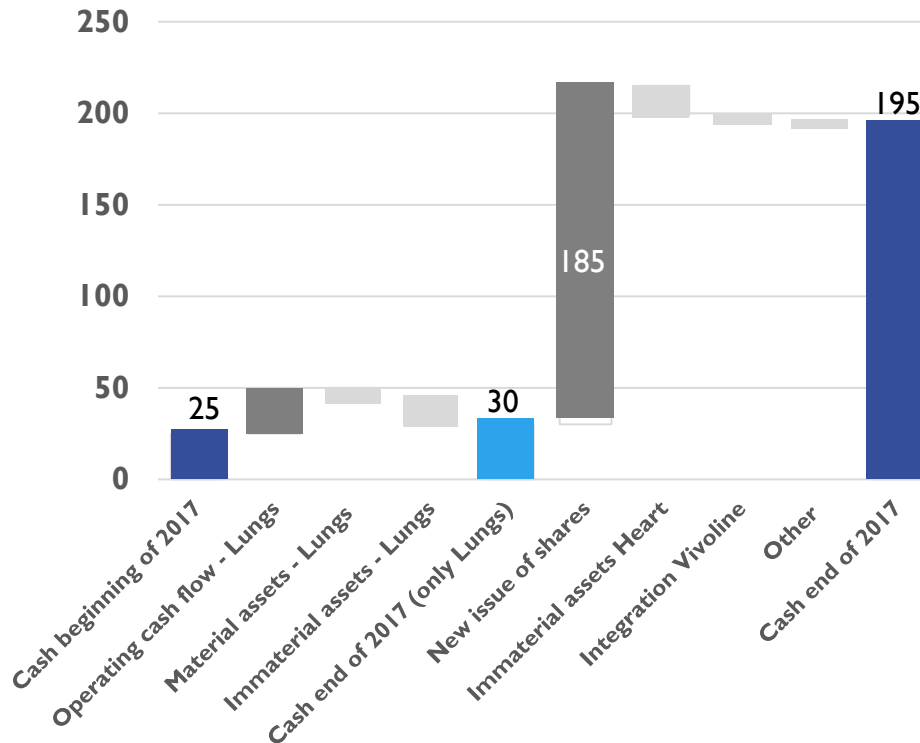
*More resources
allocated to
Customer support*

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

(SEK Millions)	2017	2016
Net sales	148.3	138.2
Net sales non-Durable goods	141.0	122.5
Gross profit	113.4	102.2
Gross Margin %	76%	74%
Gross Margin non-Durable goods %	78%	80%
Selling expenses excl. items eff. comp%	-29%	-24%
Admin. expenses excl. items eff. comp%*	-13%	-12%
R&D exp. excl. Amort. & items eff. comp%*	-18%	-19%
Items effecting comparability*	-2%	-8%
R&D Amortization %*	-7%	-7%
Other income/expenses %	-2%	-2%
Operating Result %	5%	2%
EBITDA excl. items eff. comp.*	24.8	26.4
EBITDA excl. items eff. comp%	17%	19%
EBITDA	22.0	16.0
EBITDA %	15%	12%

* Items effecting comparability: 2017 2.8 (10.4) MSEK. R&D Amortization : 2017 10.6 (10.3) MSEK.

CASH FLOW



- **Positive Cash flow from lungs in 2017**
- **Investments in heart amounted to 15 million SEK**
- **New issue of shares amounted to 185 million SEK**
- **Cash flow at the end of 2017 - 195 million SEK**

PRODUCTS & MARKETS FOR FUTURE GROWTH

XVIVO - FUTURE GROWTH OPPORTUNITIES



Expansion of Lung transplantation indication, EVLP improvement projects, increase of DCD



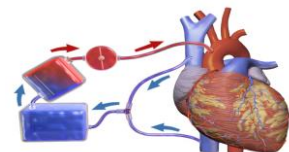
Heart Transplant project, early clinical phase



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

* 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 FDA has already HDE approval -> preparing for PMA application

NOVEL study inclusions completed:

- 110 + 110 patients
 - follow-up 1 year (May 2018)
- Form basis for PMA application
 - study data collection ongoing
 - submission to the FDA planned q2/q3

PAS (Post approval study)

- 126 + 126 pat. inclusion completed
- follow-up 3 years
- Study protocol induced restrictions on inclusions/exclusions of marginal donors/transplant recipients removed



LUNG TRANSPLANTATION

- Evolution of lung warm perfusion (EVLP)

Support to clinical development of EVLP:

- Using more DCD donors (Donation after Circulatory Death)
– controlled / uncontrolled
- Anti-infection therapy through EVLP e.g. Pneumonia and anti-virus therapy
- Investigate immunological response with EVLP targeting long term survival
- XPS evolution, better decision making tools during EVLP:
New markers and parameters



XVIVO - HEART TRANSPLANTATION

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

First clinical study started with new technology:

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



Pre-clinical proof of concept studies indicate:

- Better organ quality (Myocardium tests performance = hearts not preserved)
 - Longer preservation time possible (24h in pig studies)
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Main focus of next phase in heart transplant area:

- Adapt the heart perfusion technology for international clinical studies
- Production development of heart perfusion solution
- Preparing for next steps in clinical development

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 – study data analysis ongoing

PRIMECC® developed to avoid side-effects when priming heart-lung machines:

- Patent granted in EU, USA, China & Japan.
- CE marked Class III Medical Device.
- Inclusion of 40+40 patients completed 2017.

Next steps:

- Analysis of the 40+40 patients ongoing - ready q1
- Preparations for next steps in clinical development
 - 1) Small studies focusing on specific study observations
 - 2) Broader multi-center studies on key markets



SUMMARY OTHER NEW INDICATIONS

Liver transplantation

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



Isolated Tissue Therapy – Cancer

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



OUTLOOK 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
- Lungs – Implementation of CTP codes in US
- **R&D - New indications**
- Heart - Accelerating Heart transplant project with aim of international clinical study
- PrimECC - Analysis of PrimECC clinical data and follow-up clinical studies to increase documentation
- Liver - STEEN Solution™ clinical development for Liver
- Kidney – pre-clinical studies with STEEN Solution
- ITT - Isolated tissue therapy (Cancer / STEEN Solution™ IVLP)

→ Long-term goal is to solidify position in Thoracic surgery and build new a new business in new indications using the STEEN Solution technology.

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