

INTERIM REPORT JANUARY – JUNE 2018

TELEPHONE CONFERENCE

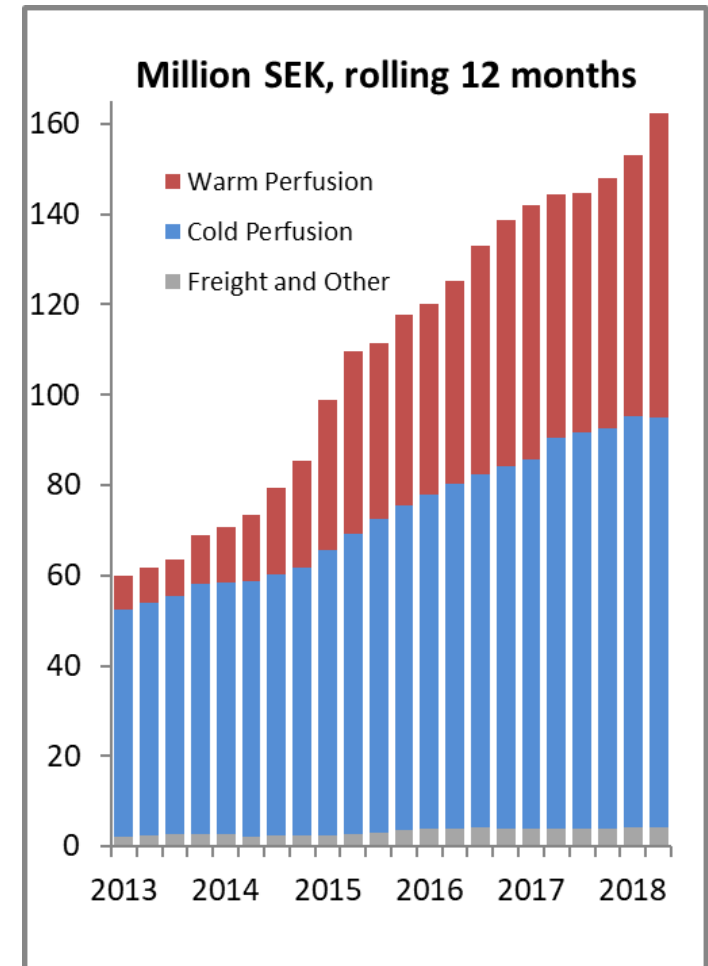
“NO ONE SHOULD HAVE TO DIE
WAITING FOR A NEW ORGAN”

July 20, 2018

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO

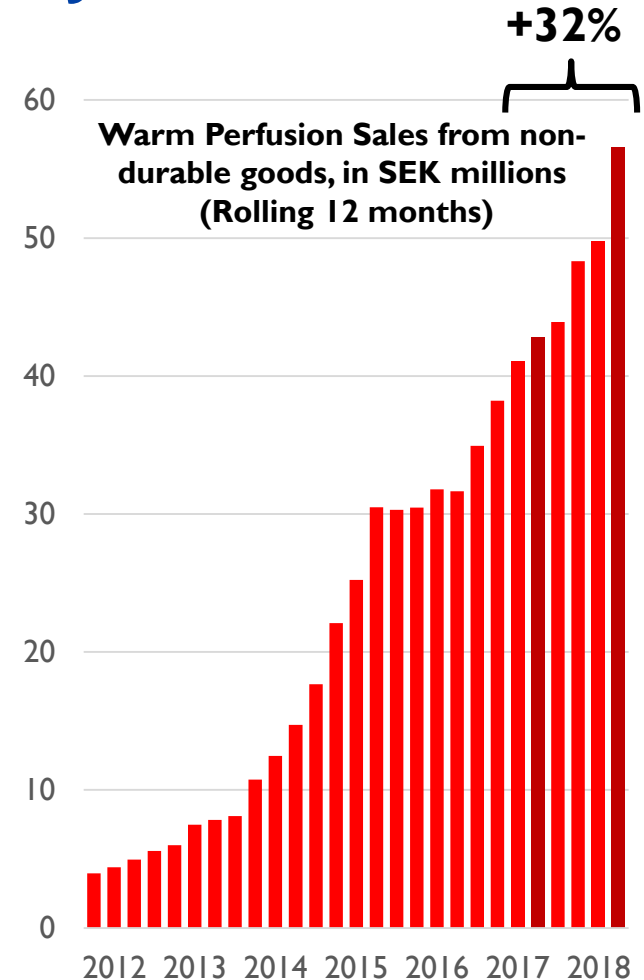
HIGHLIGHTS 2018 – Q2

- **PMA application for STEEN Solution™ and XPS™ submitted to the FDA**
- **The PrimECC® study shows that the product is safe and displays positive clinical results**
- **Perfadex Plus has been launched in EU and FDA approved**
- **United Therapeutics and XVIVO Perfusion initiated collaboration on EVLP**
- **A prototype of the new heart preservation machine has been successfully tested with porcine hearts**



SALES HIGHLIGHTS 2018 – JAN - JUN

- **Net Sales non-durable goods Jan-Jun increased by +16% in local currencies to 80.1 MSEK.**
- **Net Sales Jan - Jun grew +20% in local currencies to 88.6 MSEK.**
- **Q2 record quarter for non-durable Warm perfusion sales:**
 - **Q2 Growth + 60% (YoY)**
 - **12 month rolling growth +32% (YoY)**



PROFIT & LOSS

	2018 Jan-Jun	2017 Jan-Jun	2017 Whole year
(SEK Millions)			
Net sales	88.6	74.5	148.3
Net sales non-Durable goods	80.1	70,0	141.0
Gross profit	63.1	56.3	113.4
Gross Margin %	71%	76%	76%
Gross Margin non-Durable goods %	77%	79%	78%
Selling expenses excl. items eff. comp%	-25%	-30%	-29%
Admin. expenses excl. items eff. comp%*	-10%	-13%	-13%
R&D exp. excl. Amort. & items eff. comp%*	-21%	-19%	-18%
Items effecting comparability*	0%	-3%	-2%
R&D Amortization %*	-6%	-7%	-7%
Other income/expenses %	-1%	-2%	-2%
Operating Result %	8%	3%	5%
EBITDA excl. items eff. comp.*	15.2	11.3	24.8
EBITDA excl. items eff. comp%	17%	15%	17%
EBITDA	15.2	9.4	22.0
EBITDA %	17%	13%	15%

**Sales non-durable
+16% local currencies**

**Customer support
build up, cost lower
due to vacancies**

**Admin costs lower due
to Scale effects from
increased sales**

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

Items effecting comparability: 2018 0.0 (-1.9) MSEK. R&D Amortization : 2018 -5.4 (-5.3) MSEK.

MILESTONES - UNITED THERAPEUTICS

United Therapeutics and **XVIVO** Perfusion start collaboration

- UT will buy multiple XPS™ machines, first XPS™ delivered in Q2
- After training, implementation of IT systems and formal approval, it is estimated that UT will employ their XPS clinically from Q4
- UT and XVIVO agreed to cooperate in promoting the use of EVLP



MILESTONES - PERFADEX PLUS

Launch of Perfadex Plus

- Upgraded ready to use version of Perfadex
- CE marked and FDA (510k) registered
- Patent application filed
- Launched in European countries
- Expected US launch in Sep 2018



PRODUCTS & MARKETS FOR FUTURE GROWTH

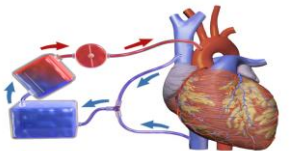
XVIVO - FUTURE GROWTH OPPORTUNITIES



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



Heart Transplant project, early clinical phase



PrimECC improve clinical proof, late 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

* 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 marginal lungs – PMA application submitted

NOVEL study & Post Approval Study (PAS) :

- 110 + 110 patients; study concluded
- PMA application submission
- PMA application under review by the FDA
- PMA application approval

- PAS (Post Approval Study)
 - 126 + 126 inclusion completed
 - Follow-up 3 years (May 2020)

- Restrictions on patients and recipients removed since PAS inclusion finalized



LUNG TRANSPLANTATION

Next steps for lung warm perfusion (EVLP)

XVIVO will continue to clinically develop EVLP:

- Use of DCD* donors for transplantation
 - controlled / uncontrolled
- Ex Vivo Infection therapy through EVLP e.g. Pneumonia therapy and virus reduction
 - Study using Hep C infected lungs ongoing
- Investigate immunological response with EVLP targeting long term survival
- XPS upgrading program with more online parameters for better decision making



*Donation after Circulatory Death

XVIVO - HEART TRANSPLANTATION

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

Pre-clinical proof of concept studies indicate:

- No non-oxygenated time -> Better organ quality
- Longer preservation time possible (24h in pigs)



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

Stig Steen, Audrius Paskevicius, Qiuming Liao & Trygve Sjöberg

First clinical started with new technology:

- First patients transplanted with the new technology in a proof of concept study
- Device approved for, and used during air transportation



Main focus of next phase in heart transplant area:

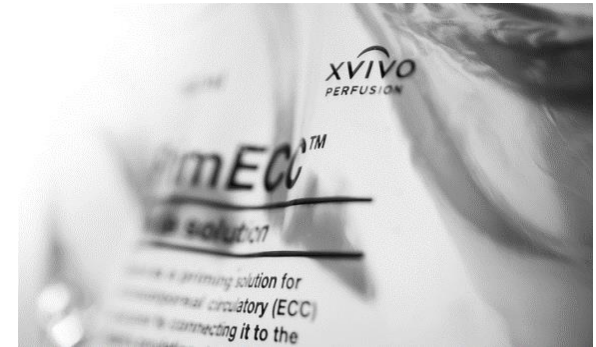
- New commercial prototype for international study:
 - successfully tested during 12 hours on porcine hearts
- Production development of new heart perfusion solution:
 - progressing according to plan
- Clinical multicenter trials in EU and USA planned to Q1, 2019:
 - Preparations ongoing



PRIMECC – POSITIVE STUDY RESULTS

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

- Patent granted in EU, USA, China & Japan
- CE marked Class III Medical Device
- Clin. Study with 40+40 patients completed



Result from clinical study - heart-lung machine primed with PrimECC®:

- PrimECC® is safe to use
- Improved fluid balance during and after the operation
- Analysis showed that side effects were avoided (in spite of low no. of patients)

OUTLOOK 2018 - FOCUS AREAS

Thoracic Surgery

- Lungs – Continue to increase footprint, support clinics to use of EVLP and upgrading of XPS
- Lungs – Reinforced clinical development of EVLP, e.g. DCD & Hep C trials
- Heart – Heart transplant project – preparations for US & EU clin. trials, planned Q1, 2019
- PrimECC – Clinical documentation program – EU & US clinical trials planned Q4, 2018

R&D - New indications

- Liver – STEEN Solution™ clinical development for Liver Tx
- Kidney – continued pre-clinical studies with STEEN Solution
- ITT – Isolated tissue therapy (Cancer / STEEN Solution™ IVLP)

Long-term goals are:

→ to further build and widening position in Thoracic surgery

→ build 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