

INTERIM REPORT JANUARY – DECEMBER 2018

TELEPHONE CONFERENCE

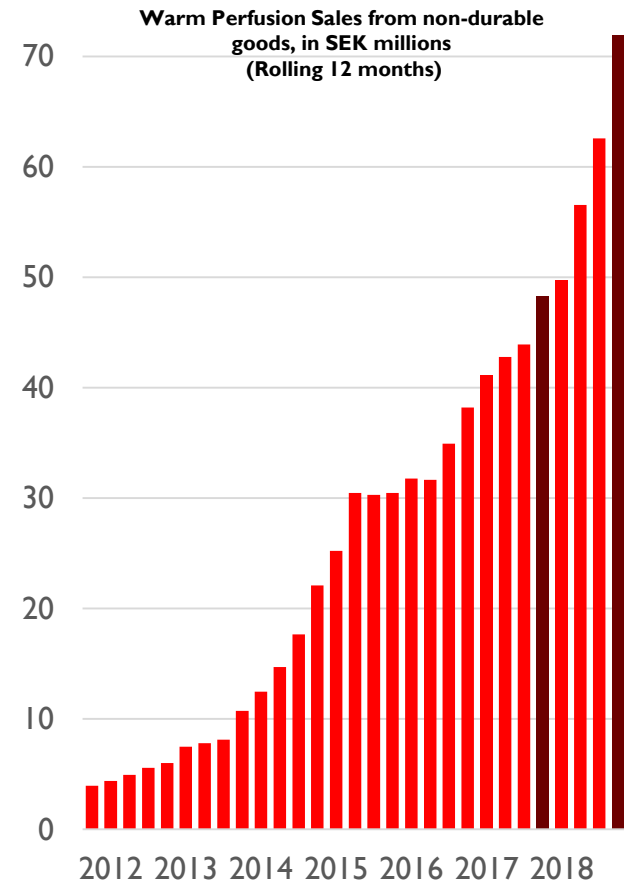
**“NO ONE SHOULD HAVE TO DIE
WAITING FOR A NEW ORGAN”**

February 8, 2019

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO

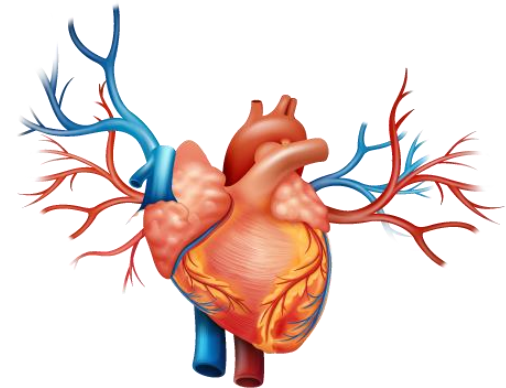
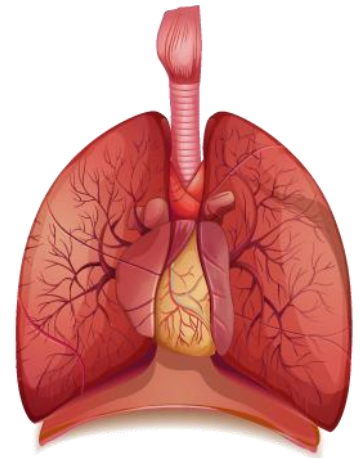
HIGHLIGHTS Q4 – RECORD SALES QUARTER

- **All time high sales and record growth**
 - Net Sales all products Oct - Dec grew +40% (+33% in local curr.) to 58 MSEK.
 - Net Sales non-durable goods Oct - Dec grew +33% (+26% in local curr.) to 52 MSEK, which was all time high.
- **Warm sales non durable portion 50% for the first time**
 - Warm growth + 54% (YoY)



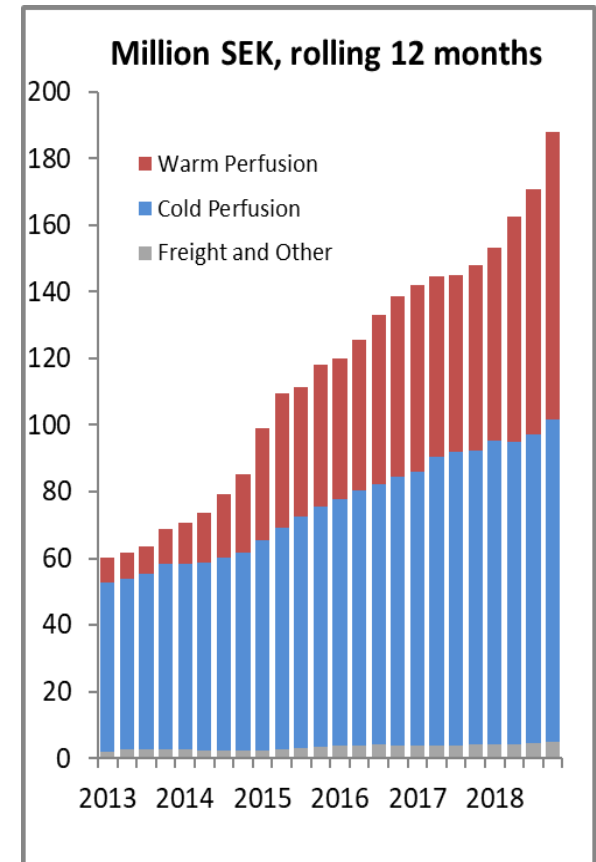
HIGHLIGHTS JAN – DEC 2018

- **PMA application for STEEN Solution™ and XPS™ submitted to the FDA – dialogue ongoing**
- **The PrimECC® study shows that the product is safe and displays positive clinical results**
- **Perfadex® Plus has been launched in EU and USA**
- **United Therapeutics and XVIVO Perfusion initiated collaboration on EVLP**
- **The heart preservation machine has been successfully tested with porcine hearts during 24 h – multicenter study preparation ongoing**



SALES HIGHLIGHTS JAN – DEC 2018

- **Net Sales all products Jan - Dec grew +27% (+23% in local curr.) to 188 MSEK.**
- **Net Sales non-durable goods Jan - Dec grew +22% (+19% in local curr.) to 173 MSEK.**
- **Continued strong growth for non-durable Warm perfusion sales, with 12 month rolling growth +48% (YoY)**



PROFIT & LOSS

(SEK Millions)	2018 Jan-Dec	2017 Jan-Dec
Net sales	187.9	148.3
Net sales non-Durable goods	172.7	141.0
Gross profit	136.0	113.4
Gross Margin %	72%	76%
Gross Margin non-Durable goods %	77%	78%
Selling expenses * %	-26%	-29%
Admin. expenses * %	-12%	-13%
R&D exp. excl. Amort. * %	-20%	-18%
Items effecting comparability * %	0%	-2%
R&D Amortization ** %	-6%	-7%
Other income/expenses %	-2%	-2%
Operating Result %	7%	5%
EBITDA excl. items effecting comperability	30.9	24.8
EBITDA excl. items effecting comperability %	16%	17%
EBITDA	30.9	22.0
EBITDA %	16%	15%

Non-durable Sales +22%

Continued high Gross Margin

Continued customer support build up, cost % lower due to vacancies start of year (now filled)

R&D clinical and product development build up

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

*Excluding items effecting comparability: 0.0 (2.8) MSEK.

**R&D Amortization: 10.9 (10.6) MSEK.

ACCOMPLISHMENTS OF 2018 & NEXT STEPS IN LUNG TRANSPLANTATION

PERFADEX® PLUS LAUNCH

A ready to use Perfadex® with increased patient safety and customer convenience

- **Successfully launched in Europe and USA**
- **Well received by customers and clinicians**
 - Ready to use and click port – reduced complexity and preparation time while increasing patient safety
- **Patent applications filed**
- **Plan for 2019 - launch in all other markets after regulatory approval**



LUNG TRANSPLANTATION

WARM PERFUSION - INCREASED FOOTPRINT

- **Collaboration between United Therapeutics and XVIVO Perfusion initiated, with 2 XPS™ sold.**
- **8 new XPS™ and LS™ machines on the market**
- **Three more Technical Advisors added to the team**
- **Established Global Marketing department**
- **Established Operations team for broader product line**



Number of EVLPs increased

LUNG TRANSPLANTATION

WARM PERFUSION - INCREASED FOOTPRINT CONT.

- **CPT*** Reimbursement codes obtained for doctor's time during EVLP procedure in US
- **PMA** application for **STEEN Solution™** and **XPS™** submitted to the **FDA**
- **Continued development of the XPS™ to enable online parameters for better decision making**
 - XVIVO Monitoring and Analysis Tool (XMAT)
 - Online weight sensor
 - Online CO₂ sensor



Number of EVLPs increased

* CPT = Current Procedural Terminology

XPS™ and LS™ FOOTPRINT



LUNG TRANSPLANTATION

NEXT STEPS FOR WARM LUNG PERFUSION (EVLP)

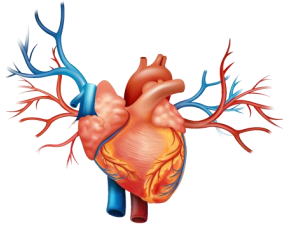
- **Broaden EVLP indications**
 - Use of DCD* lungs for transplantation
 - Anti-Infection therapy through EVLP e.g. pneumonia therapy and virus reduction (+20 Hep C lungs transplanted)
 - Immunological response during EVLP
- **Improve ease of use**
 - Protocol development
 - XPS™ automated steps in set-up and control
 - Clinical online parameter trending to improve decision making



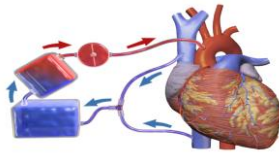
*Donation after Circulatory Death

PRODUCTS & MARKETS FOR FUTURE GROWTH

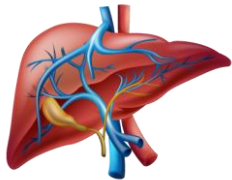
XVIVO - FUTURE GROWTH OPPORTUNITIES



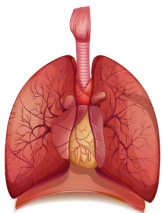
Heart Transplant project, optimized preservation to prolong time outside the body.



PrimECC®, optimized priming solution to reduce known side effects.



STEEN Solution™ for Liver and Kidney Transplant, evaluation of marginal and DCD organs.



ITT* - Perfusion of isolated organs / tissues (e.g. Drug administration) with **STEEN Solution™**

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

XVIVO - HEART TRANSPLANTATION

Development stage:
Early Clinical Phase

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

Heart Transplantation device:

- Transportable Machine & organ adapted Solution to enable longer preservation time and keep heart in better condition before transplantation
- Device approved for air transportation



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

XVIVO - HEART TRANSPLANTATION

ACCOMPLISHMENTS 2018

Development stage:
Early Clinical Phase

- **New clinical trial version machine rollout**
- **Machine and Solution successfully tested on pig heart for 24 hours with great results**
- **Clinical multi center study preparation**
 - Clinical protocol developed
 - Trial participants trained at Igelösa
 - Machine, Disposables, and Solutions production set up
 - Application submitted to the Swedish Medical Products Agency



Serval hundred thousand operations using a heart-lung machine are performed each year. PrimECC® is developed to prime the heart-lung machine before open heart surgery.

Accomplishments

- **Patented**
- **CE marked**
- **Clinical study with 40+40 patients showed**
 - PrimECC® is safe to use
 - Improved fluid balance and reduction of side effects using a heart-lung machine primed with PrimECC®

Next steps

- **Set up a large scale production in eco friendly bags**
- **Clinical study on sub groups**
 - Good response from clinics that will participate in multicenter study
 - Multicenter study to focus on findings from Sahlgrenska clinical study but with higher number of patients

OUTLOOK 2019 - FOCUS AREAS

Main Focus

Thoracic Transplantation / Surgery

- Lungs – Continue to increase footprint and support use of EVLP technology
- Heart – Preparation for multicenter study for regulatory approval
- PrimECC® – Preparation for multicenter study for clinical documentation

Secondary Focus

Abdominal Transplantation & new indications

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

→ **Long-term goal is to solidify position in Thoracic surgery**

→ **Build a new business using the STEEN Solution technology in abdominal transplantation and 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