

INTERIM REPORT JANUARY – SEPTEMBER 2018

TELEPHONE CONFERENCE

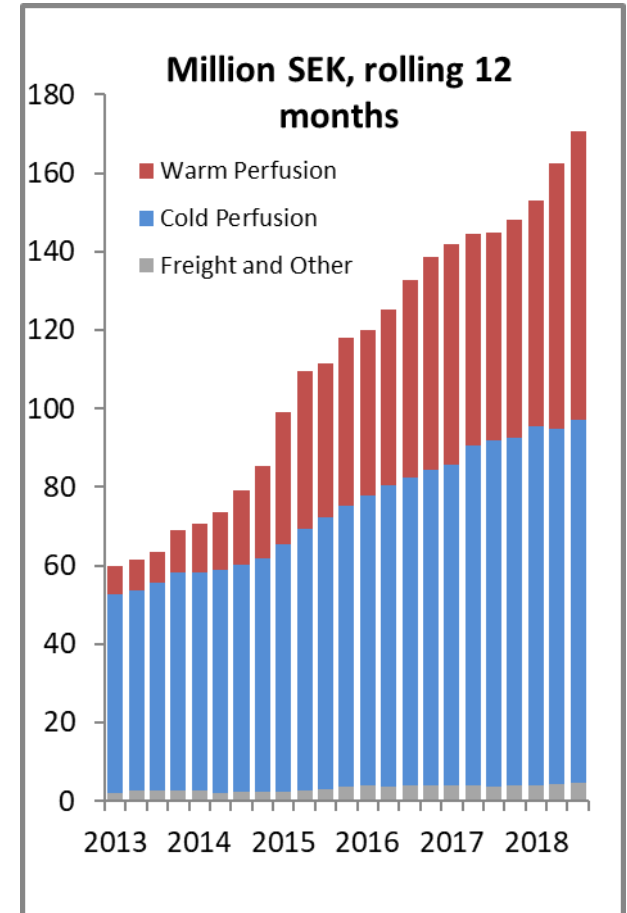
**“NO ONE SHOULD HAVE TO DIE
WAITING FOR A NEW ORGAN”**

October 26, 2018

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO

HIGHLIGHTS JAN – SEP 2018

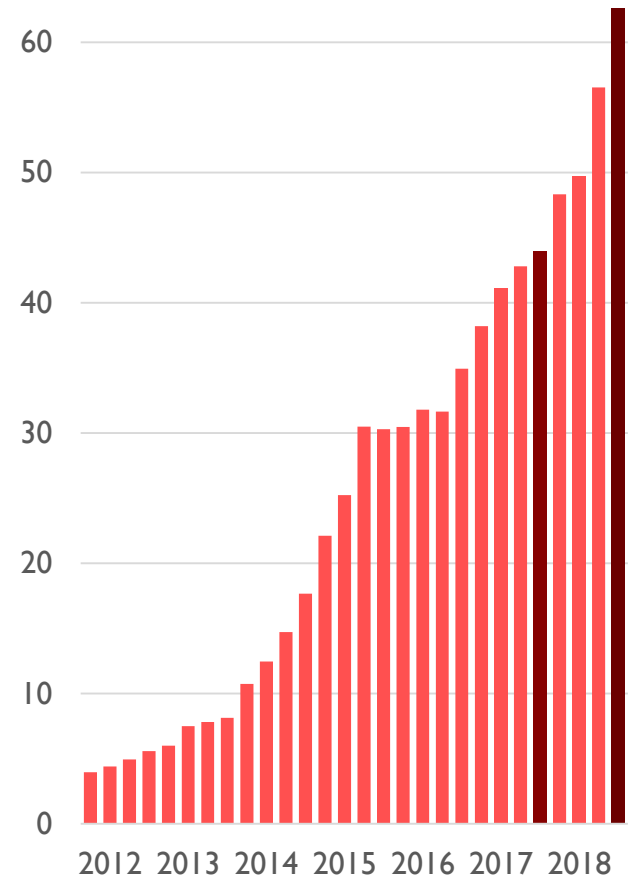
- **PMA application for STEEN Solution™ and XPS™ submitted to the FDA**
– dialogue ongoing
- **The PrimECC® study shows that the product is safe and displays positive clinical results**
– preparation new multicenter study ongoing
- **Perfadex Plus has been launched in EU and USA**
- **United Therapeutics 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 – SEP 2018

- **Net Sales all products Jan - Sep grew +21% (+19% in local curr.) to 129.5 MSEK.**
- **Net Sales non-durable goods Jan - Sep grew +19% (+16% in local curr.) to 120.4 MSEK.**
- **Continued strong growth for non-durable Warm perfusion sales:**
 - **Q3 alone growth + 65% (YoY)**
 - **12 month rolling growth +42% (YoY)**

Warm Perfusion Sales from non-durable goods, in SEK millions (Rolling 12 months)



PROFIT & LOSS

		2018	2017	2017
	(SEK Millions)	Jan-Sep	Jan-Sep	Whole year
	Net sales	129.5	106.8	148.3
Non-durable Sales +19%	Net sales non-Durable goods	120.4	101.6	141.0
	Gross profit	94.2	81.6	113.4
	Gross Margin %	73%	76%	76%
Customer support build up continued, cost % lower due to vacancies start of year (now filled)	Gross Margin non-Durable goods %	77%	79%	78%
	Selling expenses excl. items eff. comp%	-26%	-31%	-29%
	Admin. expenses excl. items eff. comp%*	-11%	-13%	-13%
	R&D exp. excl. Amort. & items eff. comp%*	-21%	-19%	-18%
	Items effecting comparability*	0%	-2%	-2%
	R&D Amortization %*	-6%	-7%	-7%
	Other income/expenses %	-2%	-2%	-2%
	Operating Result %	6%	2%	5%
	EBITDA excl. items eff. comp.*	20.4	15.7	24.8
	EBITDA excl. items eff. comp%	16%	15%	17%
	EBITDA	20.4	13.4	22.0
Lung Tx business profitable despite high investments in Marketing and R&D	EBITDA %	16%	13%	15%

Items effecting comparability: 0.0 (2.3) MSEK. R&D Amortization: 8.2 (7.9) MSEK.

PERFADEX PLUS LAUNCH

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

- **Upgraded ready to use version of Perfadex**
- **CE marked and FDA (510k) registered**
- **Patent application filed**
- **Launched in Europe and USA (Sep 2018)**
- **Launch in other markets planned within 12 months**



PRODUCTS & MARKETS FOR FUTURE GROWTH

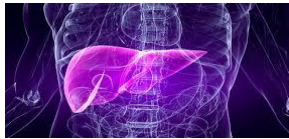
XVIVO - FUTURE GROWTH OPPORTUNITIES



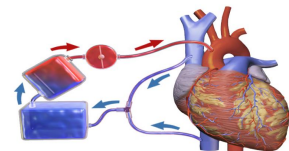
Expansion of Lung transplantation indication, EVLP improvement projects, increase of DCD



Heart Transplant project, early clinical phase



STEEN Solution™ for Liver Transplant, early clinical phase



PrimECC improve clinical proof, late 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

NOVEL study & Post Approval Study (PAS) :

- PMA study 110 + 110 patients included
- PMA application submission
- Dialog with FDA regarding application ongoing

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

- Restrictions on patients and recipients removed since PAS inclusion finalized

- CPT codes for EVLP active → Enables reimbursement of clinical team's time for EVLP



LUNG TRANSPLANTATION

Next steps for lung warm perfusion (EVLP)

XVIVO will continue to clinically develop EVLP:

- Use of DCD* lungs for transplantation
 - controlled / uncontrolled
- Ex Vivo Infection therapy through EVLP e.g. Pneumonia therapy and virus reduction
 - 20 Hep C infected lungs transplanted
- Investigate immunological response during EVLP targeting short term organ function & long term survival
- Continued development of the XPS to enable online parameters for better decision making, e.g. weight change



*Donation after Circulatory Death

XVIVO - HEART TRANSPLANTATION

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

Clinical development of heart transplantation

Clinical development with new technology:

- Safety study on 6 patients ongoing
- Preparations ongoing for multicenter studies in EU and the US:
 - Production development of heart perfusion solution & heart disposable kit started
 - All participating clinics trained on heart transplant device at Igelösa Research center.



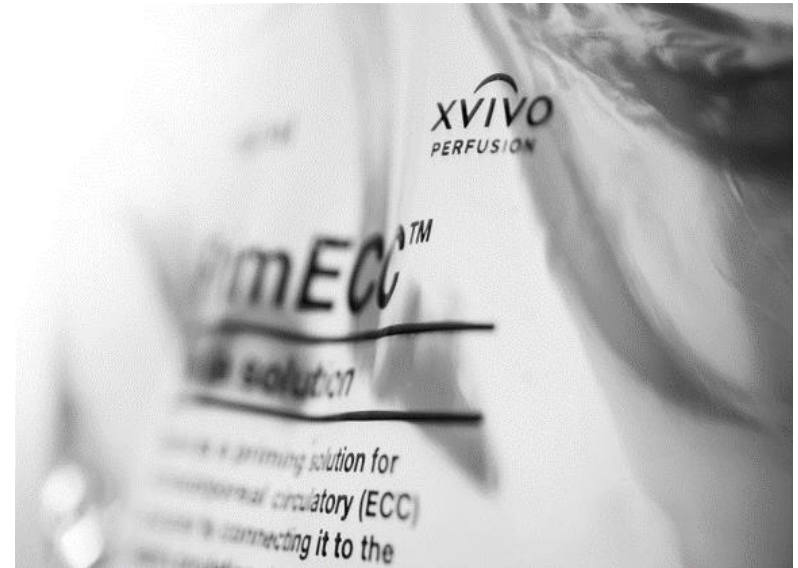
PRIMECC – STUDY INCLUSION FINALIZED

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 analysis of Clinical study:

- PrimECC® is safe to use
- Improved fluid balance and reduction of side effects using a heart-lung machine primed with PrimECC®

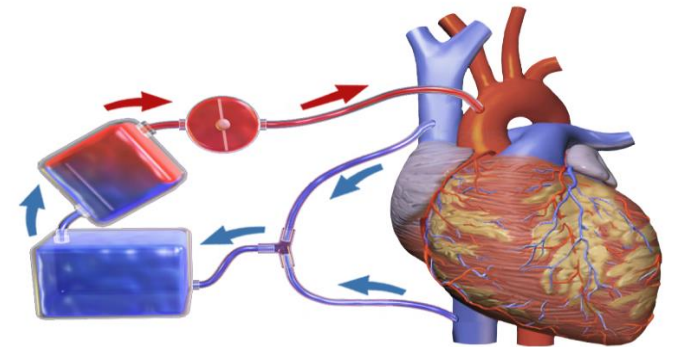


PRIMECC – MULTICENTER STUDY PLANNED

Continued clinical documentation

Main focus to start multicenter study in end 2018 / beg. 2019

- 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 2018 - FOCUS AREAS

Thoracic Transplantation / Surgery

- Lungs – Continue to increase footprint and support use of EVLP technology
- Lungs – Reinforced clinical development of EVLP, e.g. DCD usage trial
- Lungs – Hepatitis C infected donors study ongoing
- Heart – Accelerating Heart transplant project – multicenter trial planned Q1, 2019
- PrimECC – Clinical documentation – multicenter trial planned Q4 2018 / Q1 2019

Abdominal Transplantation & 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 goal is to solidify position in Thoracic surgery and 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