

INTERIM REPORT JANUARY – SEPTEMBER 2015

TELEPHONE CONFERENCE

OCTOBER 23, 2015

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO



HIGHLIGHTS

- ❑ **STEEN Solution™ 2nd indication into human clinical trial:**
First liver transplant performed after warm perfusion with STEEN Solution™ in Q3.
- ❑ **Rolling 12 months total sales 113 MSEK & sales non-durable goods 102 MSEK, passed the milestone 100 MSEK in Q3.**
- ❑ **New EVLP training facility in Denver: training program with US customers started in July.**

	<u>Jan-Sep</u>	<u>Jul-Sep</u>
❑ Total growth	+48%	+19%
❑ Growth non-Durable* goods	+33%	+16%
❑ EBITDA excl. legal one time costs	15%	16%

* Durable goods = XPS™. Non-Durable goods = all other products.

SALES HIGHLIGHTS 2015

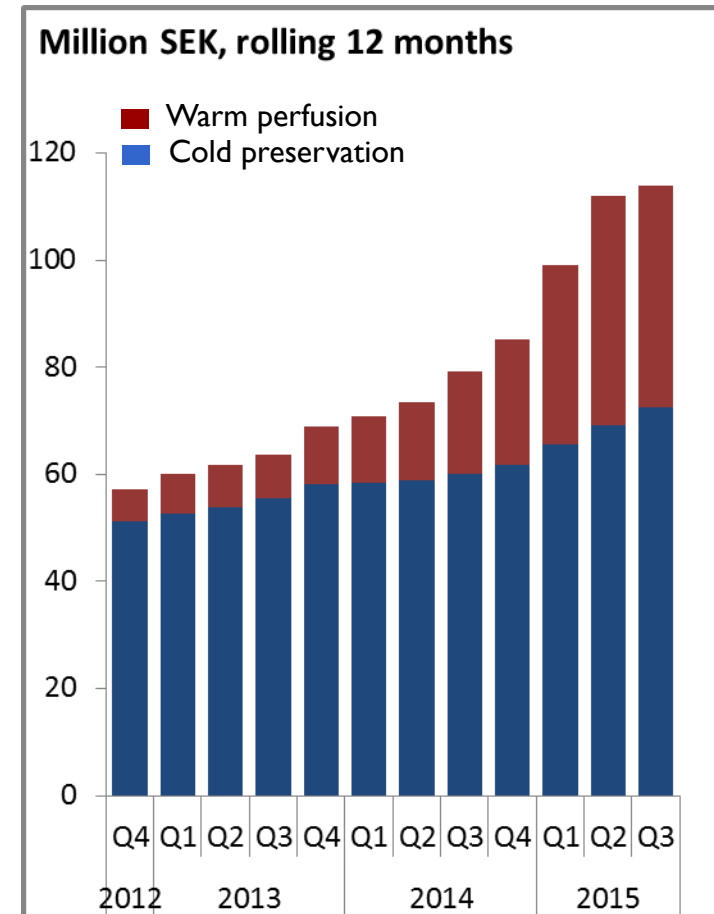
□ Total Sales Jan-Sep

- Sales 88 MSEK +48% growth
- XPS™ to 2nd largest clinic in the world (after the quarter). In total 22 clinics with XPS™
- Warm perfusion revenue share * 38%

□ Sales non-Durable** goods Jan-Sep

- Sales 77 MSEK +33% growth
- Warm perfusion* growth +62%
- Warm perfusion revenue share* 29%

Net sales



* Warm perfusion products are products used for EVLP e.g. STEEN Solution™ and XPS™ related products.

** Durable goods = XPS™. Non-Durable goods = all other products.

PROFIT & LOSS JAN-SEP, 2015

January - September

Full year

(SEK millions)	2015	2014	2014
Net sales	87.6	59.2	84.7
Net sales non-Durable goods	76.8	57.7	83.2
Gross Margin %	69%	75%	76%
Gross Margin non-Durable goods %	77%	77%	77%
Selling expenses %	26%	29%	27%
Administrative expenses %	11%	14%	13%
R&D expenses excl. Amort & Legal %*	16%	17%	18%
R&D expenses % Legal one-time*	2%	3%	5%
R&D Amortization %*	9%	3%	5%
Other expenses %**	1%	0%	0%
Operating Result %	3%	11%	8%
Operating Result excl. one-time cost*%	5%	15%	13%
EBITDA	11.3	8.3	11.4
EBITDA %	13%	14%	13%
EBITDA excl. one-time cost*	13.0	9.8	15.7
EBITDA excl. one-time cost in relation to sales non-Durable goods* %	17%	17%	19%

Continued high gross margin

Lower percentage in Admin costs show pronounced economies of scale

Good profit level simultaneously with higher investments in Marketing and R&D.

* One-time costs Jan-Sep 2015 were SEK 1.7 (1.5) million. Amortization on the US STEEN Solution asset Jan-Sep 2015 was SEK 7.3 (0.8) million.

** Ex change rate related costs Jan-Sep 2015 was SEK 0.7 million.

MILESTONES PASSED SINCE SPIN-OFF 3 YEARS AGO

- ❑ XVIVO is the first and only company in the world to have a product for warm perfusion of an organ approved by the FDA.**
- ❑ Sales doubled to 113 MSEK (rolling 12-months sales).**
- ❑ Competence and Marketing capacity built-up on both sides of the Atlantic. Now total 20 employees and EVLP training facility.**
- ❑ Second indication for STEEN Solution into clinic trial:
First liver transplant performed after warm perfusion with STEEN Solution.**

USA: HIGH INTEREST FOR XPS™

- ❑ **6 XPS™ contracts so far in 2015 to Texas, Illinois, Florida x2, California and Virginia (new states with XPS™)**
- ❑ **Now, 18 clinics have access to XPS™. Those clinics cover around 40% of all lung transplants made in the U.S.**
- ❑ **Warm perfusion* show high growth
Jan-Sep:
+300% incl. durable goods and,
+120% excl. durable goods****
- ❑ **Expert User training program set up in Denver, running & fully booked**



* Warm perfusion products are products used for EVLP e.g. STEEN Solution™ and XPS™ related products.

** Durable goods = XPS™. Non-Durable goods = all other products.

EUROPE: INCREASING INTEREST FOR XPS™

- ❑ **3 CLINICS with XPS™ (October)**
- ❑ **XPS™ delivered in October to Vienna - the worlds 2nd largest clinic.**
- ❑ **Increasing interest for XPS™ in Europe, but longer lead time to decision compared to the U.S. Main reason is bureaucratic process and economical constrains.**



R&D FOCUS LUNG TRANSPLANTATION

Even though EVLP* with STEEN Solution™ and XPS™ is approved on all major markets, XVIVO Perfusion continues to invest in EVLP research to:

- ❑ Add and improve parameters to assess a lung during EVLP
- ❑ Improve the decision making process to determine which lungs are good enough for transplantation through enhancing the capabilities & ease of use of the XPS™

* EVLP or Ex Vivo Lung Perfusion is when a lung is perfused outside the body.

R&D FOCUS LIVER TRANSPLANTATION

- ❑ 7 patients transplanted with a Liver perfused with STEEN Solution™

- ❑ Liver transplantation market has high potential:
 - Waiting list mortality high: ~20% in the US

 - Around 24,000 Liver transplants are made world wide per year (compared to around 5,000 Lung transplants per year). Main use today is DBD* livers and living donor livers.

 - Potential to use DCD* livers with STEEN Solution™

* DBD = Donation after Brain Death. DCD = Donation after Circulatory (or Cardiac) Death.

OUTLOOK 2015

- ❑ **Increase number of clinics with XPS™**
 - Continued high interest in the US and Europe to acquire XPS™ to set up EVLP
- ❑ **Increase usage of XPS™**
 - Support clinics with training & re-training programs and workshops
 - Continued support to US clinics with paperwork (PMA-protocol, IRB, Reimbursement) and EU clinics with reimbursement
 - Increase US customer support team to enable more and closer contact with clinics
- ❑ **Continued recruitment of patients to the NOVEL PMA study in the US**
- ❑ **Support Liver STEEN Solution™ research to prove safety of STEEN Solution™ in Liver transplantation**
- ❑ **Plan to enter clinical phase for Cancer STEEN Solution™ IVLP***

* IVLP or In Vivo Lung Perfusion is when a lung is perfused inside the body.

LONG TERM FOCUS (3 Y)

Deeper & broader use of STEEN Solution™ technology. Develop warm perfusion with STEEN Solution™ for new indications.

- ❑ Establish Warm perfusion with STEEN Solution™ for lung transplantation as a standard treatment.**
- ❑ Clinical development of STEEN Solution™ for Liver with aim of regulatory approval. Currently 7 patients transplanted in proof of concept study.**
- ❑ Enter clinical development of drug administration to isolated organs with the aim of regulatory approval. Aim to enter clinical phase for Cancer treatment of lungs in months to come.**
- ❑ Continued pre-clinical research of warm perfusion with STEEN Solution™ for other organs before transplantation with the aim of entering clinical phase.**

THANK YOU!