# INTERIM REPORT JANUARY – JUNE 2015

TELEPHONE CONFERENCE

AUGUST 13, 2015

MAGNUS NILSSON, CEO CHRISTOFFER ROSENBLAD, CFO





# **HIGHLIGHTS 2015**

	Jan-Jun	Apr-Jun	
Total growth	+66%	+58%	
Growth non-Durable* goods	+43%	+48%	
EBITDA excl. legal one time costs	14%	15%	
Rolling 12 months sales 109 MSEK, passed the milestone 100 MSEK in Q2.			
Share warrant program 2015/2017 fully subscribed			

<sup>\*</sup> Durable goods = XPS™. Non-Durable goods = all other products.



## **SALES HIGHLIGHTS 2015**

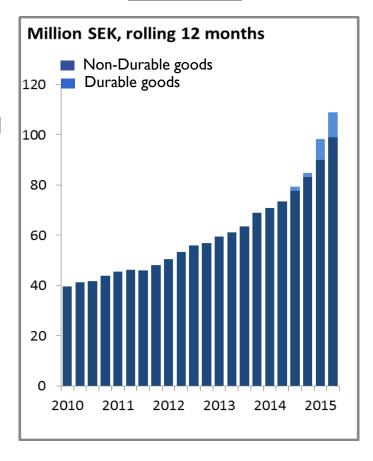
#### □ Total Sales Jan-Jun

- Sales 61 MSEK +66% growth
- 6 XPS <sup>™</sup> delivered
- 2 XPS<sup>™</sup> contract signed after the end of the period – in total 21 clinics with XPS<sup>™</sup>

#### ☐ Sales non-Durable\*\* goods Jan-Jun

- Sales 52.5 MSEK +43% growth
- Warm perfusion\* growth +98% (+123% in Q2)
- Warm perfusion revenue share\*33% (35% in Q2)

#### **Net sales**



<sup>\*</sup> Warm perfusion products are products used for EVLP e.g. STEEN Solution™ and XPS™ related products.

<sup>\*\*</sup> Durable goods = XPS™. Non-Durable goods = all other products.



**Full vear** 

January - June

# PROFIT & LOSS JAN-JUN, 2015

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

	oandar y	January - June	
(SEK millions)	2015	2014	2014
Net sales	60.9	36.7	84.7
Net sales non-Durable goods	52.5	36.7	83.2
Gross Margin %	68%	78%	76%
Gross Margin non-Durable goods %	77%	78%	77%
Selling expenses %	26%	31%	27%
Administrative expenses %	11%	15%	13%
R&D expenses excl. Amort %*	17%	19%	23%
R&D Amortization %*	9%	2%	5%
Other expenses %**	1%	0%	0%
Operating Result %	2%	11%	8%
Operating Result excl. one-time cost*%	5%	15%	† 13%
EBITDA	7.2	4.9	11.4
EBITDA %	12%	13%	13%
EBITDA excl. one-time cost*	8.8	6.1	15.7
EBITDA excl. one-time cost in relation to sales non-Durable goods* %	17%	17%	19%

<sup>\*</sup> One-time costs Jan-Jun 2015 were SEK 1.7 (1.3) million. Amortization on the US STEEN Solution asset Jan-Jun 2015 was SEK 4.9 (0.0) million.

<sup>\*\*</sup> Ex change rate related costs Jan-Jun 2015 was SEK 0.5 million.



# USA: 18 CLINICS WITH XPS™ (JULY)

- □ 6 XPS<sup>™</sup> contracts so far in 2015 to Texas, Illinois, Florida x2, California and Virginia (new states with XPS<sup>™</sup>)
- Now, 18 clinics have access to XPS™. Those clinics cover around 40% of all lung transplants made in the U.S.
- ☐ High growth Jan-Jun: +110%
- □ Continued high interest for XPS™
- □ Continued support to clinics with paperwork for NOVEL study and reimbursement





## **EUROPE:** 2 CLINICS WITH XPS™

- □ 2 XPS<sup>™</sup> delivered to Germany and Italy
- □ 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.





# LIVER TRANSPLANTATION WITH STEEN SOLUTION TO STE

- □ 3 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™

<sup>\*</sup> DBD = Donation after Brain Death. DCD = Donation after Circulatory (or Cardiac) Death.



#### R&D EVLP\*

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

<sup>\*</sup> EVLP or Ex Vivo Lung Perfusion is when a lung is perfused outside the body.



## **R&D NEW INDICATIONS**

With regulatory approval of EVLP with XPS™ and STEEN Solution™ on all major markets in the world, increased R&D resources are invested in:

- □ Clinical research Liver: Liver transplantation with STEEN Solution<sup>™</sup> 3 patients transplanted
- □ Clinical research Cancer: Lung Cancer treatment with STEEN
  Solution™ (IVLP\*) study planned to start in the coming months
- □ Pre-clinical research: Heart and Kidney transplantation with STEEN Solution<sup>™</sup> in pre-clinical state

<sup>\*</sup> IVLP or In Vivo Lung Perfusion is when a lung is perfused inside the body.



## **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
- 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\*
- Prepare application for listing on Nasdaq Stockholm's main list in 2016

<sup>\*</sup> IVLP or In Vivo Lung Perfusion is when a lung is perfused inside the body.

# THANK YOU!

