# Report on Operations 2014

Telephone conference

February 5, 2015

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## Highlights 2014

☐ Total growth +23%
Growth consumables +21%

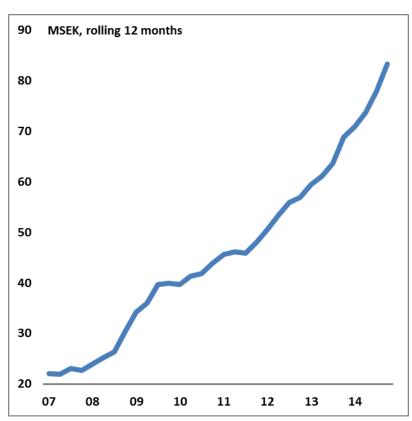
☐ Growth warm perfusion consumable products +106%

□ EBITDA excl. one-time costEBITDA13%

□ US FDA approval for XPS<sup>™</sup> and STEEN Solution<sup>™</sup>

**□** XPS™ CE mark

#### **Net sales consumable products**



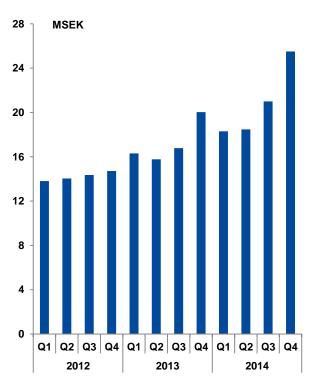


# Highlights Q4, 2014

Total growth	+28%
<b>Growth consumables</b>	+28%

- ☐ Growth warm perfusion consumable products +106%
- □ EBITDA excl. one-time cost 23%EBITDA 12%
- □ Two XPS™ contracts signed
- ☐ Arbitration board ruled in the legal Igelösa case, resulting in a one-time cost of SEK 2.8 million

#### **Quarterly Net sales consumable products**



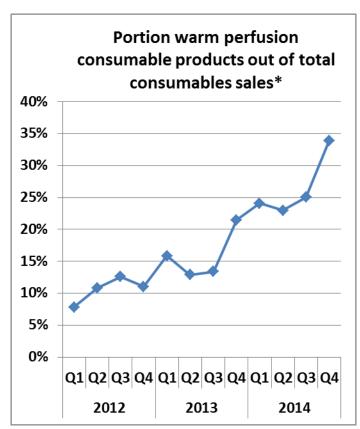


# Growth driven by warm perfusion consumables

Growth of warm perfusion consumables \* +106%

	Revenue share warm perfusion*		
	2014	2013	
Q4	34%	21%	
YTD	27%	16%	

<sup>\*</sup> Warm perfusion products are STEEN Solution™ and XPS™ related consumable products. Revenue portion warm perfusion is warm perfusion products as a portion of total consumables product sales.





#### Q4 EBITDA doubled excl. one-time costs

		October - December		January - December	
(SEK millions)	2014	2013	2014	2013	
Net sales	25.5	20.0	84.7	68.9	
Net sales consumables	25.5	20.0	83.2	68.9	
Gross Margin %	77%	76%	76%	79%	
Gross Margin consumables %	77%	<b>76%</b>	77%	79%	
Selling expenses %	23%	23%	27%	25%	
Administrative expenses %	12%	15%	13%	17%	
R&D %*	42%	25%	28%	22%	
R&D excl. one-time costs %*	31%	25%	23%	22%	
Operating Result %	1%	13%	8%	16%	
Operating Result excl. one-time cost*%	12%	13%	13%	16%	
EBITDA	3.1	3.0	11.4	13.0	
EBITDA %	12%	15%	13%	19%	
EBITDA excl. one-time cost*	5.9	3.0	15.7	13.0	
EBITDA excl. one-time cost* %	23%	15%	19%	19%	

<sup>\*</sup> Amortization on the US STEEN Solution asset Sep-Dec 2014 SEK 3.3 million (Oct-Dec 2014 SEK 2.4 million. One-time costs Jan-Dec 2014 SEK 4.3 million (Oct-Dec 2014 SEK 2.8 million)



#### USA: XPS™ and STEEN Solution™ launch

- Sales of XPS™ consumables as of FDA approval
- ☐ High interest from clinics for XPS™
- ☐ Support clinics with paperwork (IRB, Reimbursement, PMA-protocol)
- NOVEL study with aim of PMA approval
  - Shortened time frame can use patients from HDE study
  - Clinics will pay for XPS™ consumables





### **Europe:** XPS™ focus

- □ XPS™ contract in Germany
  - Reimbursement approved (regional)
- □ Increased interest for XPS™
  - Need of standardized procedure
  - FDA approval
  - Good clinical results
- □ Focus on clinics with EVLP experience





## Asia: Invest to build warm perfusion market

- First XPS™ sold to Asia in 2014
- China main focus
  - **Contract with leading** distributor for advanced hospital equipment
  - Regulatory application for **STEEN Solution™ and XPS™** submitted





# Investment into new indications for STEEN Solution™

- □ Cancer treatment In Vivo Lung Perfusion (IVLP) with
   STEEN Solution™
  - IVLP similar to current EVLP Technology
  - Regulatory route estimated to be shorter since STEEN Solution™
     approved
  - Aim to reach clinical phase Feb-Apr 2015 depending on Ethics board approval
- ☐ STEEN Solution<sup>™</sup> Ex Vivo Organ Perfusion
  - Liver and Heart STEEN Solution™ projects in pre-clinical phase.
  - Plan to enter Liver clinical phase first half 2015.



