# **REPORT ON OPERATIONS 2012**

February 20, 2013

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## BACKGROUND

- First report as an independent company
- XVIVO Perfusion was distributed to Vitrolife's shareholders Oct 1, 2012
- Trade in Xvivo shares began Oct 8, 2012 on NASDAQ OMX First North
- Start up phase finished organization built
- Full focus on FDA approval
- The US study shows promising results (32 out 42 transplanted)
- Promising results also outside the US:
  - Canada, Austria, France and Holland
- Continued great interest from clinics





### **SUMMARY Q4**

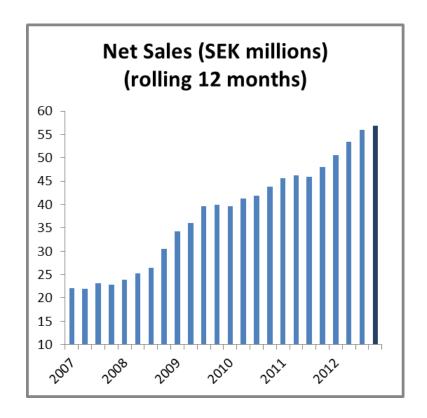
- Sales growth +10%, in local currencies, versus a strong quarter for Vitrolife's Transplantation segment in Q4 2011.
- EBITDA excluding one-time expenses 3.3 MSEK (22%)
- Marketing approval in Canada and first commercial order shipped in December
- FDA informed about supplementary questions Feb 2013
- Lawsuits against Vitrolife with regard to Perfadex®
  - Since products are sold prior to spin-off Oct 1, 2012 Vitrolife is responsible and will handle all three lawsuits
  - XVIVO Perfusion not liable to pay damages





# **FULL YEAR 2012 SALES DEVELOPMENT**

- 2012 pro forma\* Sales growth +18%, in local currencies, versus Vitrolife's Transplantation segment 2011
- STEEN Solution<sup>™</sup> technology does not cannibalize on existing Perfadex® sales since both are used in the new method as well
- STEEN Solution<sup>™</sup> for clinical use increased by 9 clinics in 2012







# **KEY FINANCIALS GROUP**

EBITDA Q4, 2012 effected by one-time costs. EBITDA Q4, 2012 excl. one-time costs was 22%.

	October - December		January - December	
(SEK millions)	2012	2011**	2012*	2011**
Net sales	14.7	13.7	56.9	48.1
Gross Margin %	78%	82%	79%	79%
Selling expenses %	22%	19%	18%	11%
Administrative expenses %	38%	32%	32%	15%
Research and development costs %	16%	12%	15%	10%
Operating Margin %	1%	17%	13%	42%
Operating Margin % excl. one time	20%	17%	28%	42%
costs***				
EBITDA %	4%	18%	15%	43%
EBITDA % excl. one-time costs***	22%	18%	30%	43%

<sup>\* 2012</sup> Pro forma equal to Vitrolife's Transplantation segment for Jan-Sep 2012 added with XVIVO Perfusion Oct-Dec 2012



<sup>\*\* 2011</sup> comparative figures are Vitrolife's Transplantation segment

<sup>\*\*\*</sup> One-time costs for Q4 2012 amount to 2.7 MSEK and for 2012 full year to 8.6 MSEK

### STATUS FDA APPROVAL PROCESS

- July 2012 FDA HDE\* application submitted
- October 2012 FDA asked follow-up questions which Xvivo answered
- February 2013 FDA notified Xvivo that a few more follow-up questions will be submitted
- The clinical trial for a "full" FDA approval is proceeding according to plan with 32 out of 42 patients transplanted
- Great interest among clinics in the USA and two new centers added to the trial (Philadelphia and Indianapolis)
- The same method as used in the US study is being used with good results in Canada, Austria, France and Holland.





# US LAWSUIT FILED AGAINST VITROLIFE / PERFADEX®

- July 2012 one lawsuit filed against Southwest Transplant Alliance,
  University of Texas and Vitrolife Inc.
- In Q4 2012, two further lawsuits filed against the same parties
- XVIVO Perfusion not liable since the products were sold before Oct 1, 2012
- Perfadex® is since 2001 used by all lung transplant centers in the USA
- Perfadex® so far been used in thousands of lung transplants





## **OUTLOOK 2013**

- Focus on FDA approval
- Increase resources for sales and marketing in Europe and the USA
- FDA approval will trigger amortization of capitalized asset for STEEN Solution™. The capitalized asset at the end of 2012 was 73 MSEK and it is estimated to be amortized over 10 years.





