# Interim report Q1, 2013

April 19, 2013

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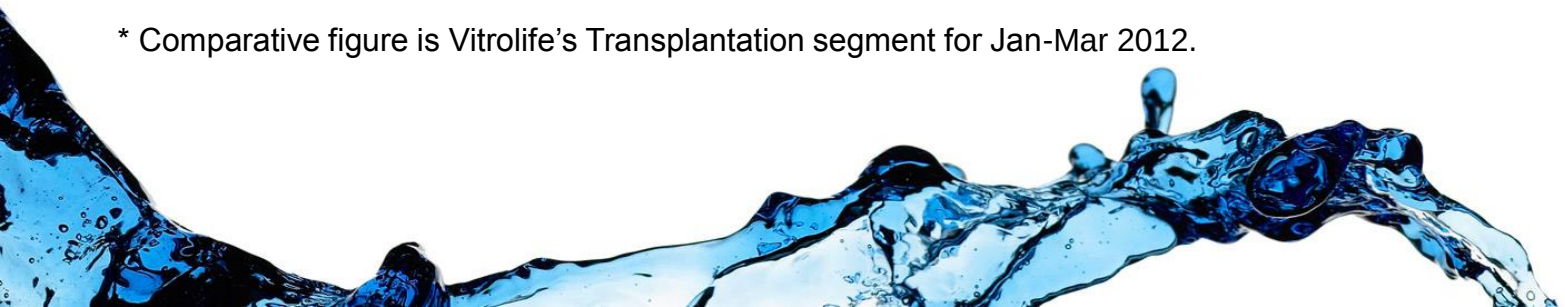
# SUMMARY Q1 2013

- Sales growth +23*% in local currencies and +18%* in SEK.
- EBITDA 3.8 MSEK which is 23% of sales.
- FDA came back with supplementary questions at the end of the quarter. The questions planned to be answered in late April / early May.
- The US study shows promising results and 39 out 42 transplanted (until mid April 2013).

XVIVO Perfusion sell directly to around 35 countries from the offices in Gothenburg and Denver.

* Comparative figure is Vitrolife's Transplantation segment for Jan-Mar 2012.



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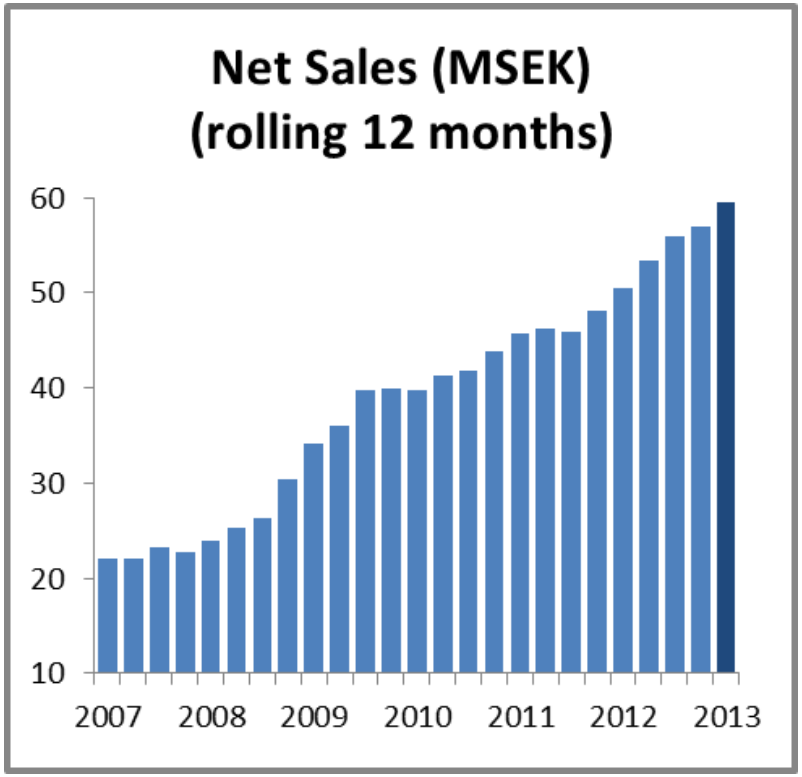
# SALES DEVELOPMENT

- 2013 Q1 Sales growth +23%*, in local currencies.
- STEEN Solution™ and related products portion of sales is growing.
  - 16% in Q1 2013 vs. 8% in Q1 2012
- STEEN Solution™ technology does not cannibalize on existing Perfadex® sales since both are used in the new method as well.




* 2012 Comparative figure is Vitrolife's Transplantation segment.

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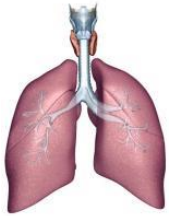
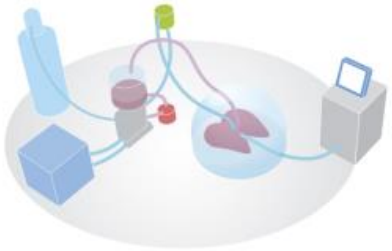
# MARKET POTENTIAL

## TRADITIONAL ORGAN PRESERVATION (COLD PERFUSION)



## NEW METHOD – WARM PERFUSION WITH STEEN SOLUTION™




| | | | |
|---|---|---|---|
| Sales per transplantation (SEK) | ~ 10 000 | → | **~ 80 000 (50'-120') SEK** |
| Potential number of lung transplantations / evaluations | ~ 4 000 | → | **~ 12 000** |
| Estimated Total market potential, <u>for lung transplantation</u> (SEK millions) | ~ 50 | → | **~ 1 000 SEK millions** |

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# KEY FINANCIALS GROUP

- EBITDA Q1, 2013 was 23%.

| | January - March | |
|---|---|---|
| (SEK millions) | 2013 | 2012* |
| **Net sales** | **16.3** | **13.8** |
| **Gross Margin %** | **80%** | **80%** |
| Selling expenses % | 20% | 12% |
| Administrative expenses % | 20% ** | 17% |
| Research and development costs % | 17% | 15% |
| **Operating Margin %** | **21%** | **35%** |
| **EBITDA %** | **23%** | **36%** |

* 2012 Comparative figures are Vitrolife's Transplantation segment.
** Administrative expense for 2013 includes cost for external board and stock listing.

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# STATUS FDA APPROVAL PROCESS

- July 2012 FDA HDE* application submitted
- October 2012 FDA asked follow-up questions which Xvivo answered
- March 2013 FDA asked additional questions for clarification. Response submission planned for late April / early May
- The clinical trial for the PMA (Pre Market Approval) application with the FDA is proceeding according to plan with 39 out of 42 patients transplanted
- University of Indianapolis added to the trial and great interest among surgeons in the USA
- The same method as used in the US study is being tested with good results in Canada, Austria, France and Holland.

* HDE = Humanitarian Device Exemption

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# OUTLOOK 2013

- Focus on FDA approval in the US
  - Increase resources for sales and marketing in the USA when approval from the FDA.
  - FDA approval will trigger amortization of capitalized asset for STEEN Solution™. The capitalized asset at the end of Q1, 2013 was 74 MSEK and it is estimated to be amortized over 10 years.
- Focus on establishing the STEEN Solution™ method in Europe, Asia and Pacific
  - New clinics and increased use of STEEN Solution™ in Western Europe and Pacific
  - New clinics in Asia and Eastern Europe
  - Auxiliary products to STEEN Solution™ for Europe evaluated
- Develop the STEEN Solution™ method for other organs

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