INTERIM REPORT JANUARY – SEPTEMBER 2017
TELEPHONE CONFERENCE

“NO ONE SHOULD HAVE TO DIE WAITING FOR A NEW ORGAN”

October 27, 2017

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO

NASDAQ OMX Stockholm (mid cap): XVIVO
HIGHLIGHTS 2017-Q3

- First patient Heart transplanted using the new machine and solution
- Inclusion of all 110+110 patients in NOVEL study completed
  - Basis for PMA application
- Inclusion of all 40+40 patients in PrimECC study completed
- 20 patients included in Liver study with STEEN Solution on DBD livers
- Clean room in Lund increased production and R&D capability
SALES HIGHLIGHTS 2017 JAN - SEP
DOUBLE DIGIT GROWTH FOR NON-DURABLE SALES

- Sales:
  - Non-durable goods +15%* or 102 MSEK

- EU & Aus: 2 new countries with XPS
  - Australia & the Netherlands
  - Continued high interest from customers for the XPS & LS

- USA - XPS contract signed with clinic in Kentucky and continued high interest from new clinics

* Local currency growth for non-durable goods +13% YTD and +11% Q3
## PROFIT & LOSS

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Net sales</strong></td>
<td><strong>106.7</strong></td>
<td><strong>99.8</strong></td>
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<tr>
<td><strong>Sales non-durable</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>+15%</strong></td>
<td></td>
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<tr>
<td><strong>Net sales non-Durable goods</strong></td>
<td><strong>101.6</strong></td>
<td><strong>88.0</strong></td>
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<tr>
<td><strong>Gross profit</strong></td>
<td></td>
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<tr>
<td><strong>76%</strong></td>
<td><strong>81.6</strong></td>
<td><strong>73.3</strong></td>
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<tr>
<td><strong>Gross Margin %</strong></td>
<td><strong>74%</strong></td>
<td><strong>74%</strong></td>
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<tr>
<td><strong>Gross Margin non-Durable goods %</strong></td>
<td><strong>79%</strong></td>
<td><strong>80%</strong></td>
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<tr>
<td><strong>Selling expenses excl. items aff. comp%</strong></td>
<td><strong>-31%</strong></td>
<td><strong>-24%</strong></td>
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<tr>
<td><strong>Admin. expenses excl. items aff. comp%</strong></td>
<td><strong>-13%</strong></td>
<td><strong>-12%</strong></td>
</tr>
<tr>
<td><strong>R&amp;D exp. excl. Amort. &amp; items aff. comp%</strong></td>
<td><strong>-19%</strong></td>
<td><strong>-18%</strong></td>
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<tr>
<td><strong>Items affecting comparability</strong></td>
<td><strong>-2%</strong></td>
<td><strong>-7%</strong></td>
</tr>
<tr>
<td><strong>R&amp;D Amortization %</strong></td>
<td><strong>-7%</strong></td>
<td><strong>-8%</strong></td>
</tr>
<tr>
<td><strong>Other income/expenses %</strong></td>
<td><strong>-2%</strong></td>
<td><strong>-2%</strong></td>
</tr>
<tr>
<td><strong>Operating Result %</strong></td>
<td><strong>2%</strong></td>
<td><strong>3%</strong></td>
</tr>
<tr>
<td><strong>EBITDA excl. items eff. comp.%</strong></td>
<td><strong>15.7</strong></td>
<td><strong>19.7</strong></td>
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<tr>
<td><strong>EBITDA excl. items eff. comp%</strong></td>
<td><strong>15%</strong></td>
<td><strong>20%</strong></td>
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<tr>
<td><strong>EBITDA</strong></td>
<td><strong>13.4</strong></td>
<td><strong>12.4</strong></td>
</tr>
<tr>
<td><strong>EBITDA %</strong></td>
<td><strong>13%</strong></td>
<td><strong>12%</strong></td>
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* Items affecting comparability: 2017 Jan-Sep 2.3 (7.3) MSEK. R&D Amortization: 2017 Jan-Sep 7.9 (7.7) MSEK.

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**Sales non-durable +15%
Continued strong gross margin
Customer support build up
Running business profitable despite high investments in Marketing and R&D

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January – September 2017 Interim report presentation
PRODUCTS & MARKETS FOR FUTURE GROWTH
XVIVO - FUTURE GROWTH OPPORTUNITIES

Expansion of Lung transplantation indication, e.g. Infection (e.g. Hep C) EVLP treatment, Increase of DCD lungs

Heart Transplant project, early clinical phase

STEEN Solution™ for Liver Transplant, clinical phase

ITT* - Drug administration to isolated organs (e.g. Cancer) with STEEN Solution™, early clinical phase

PrimECC improve clinical proof, clinical phase

* ITT or Isolated Tissue Therapy is a therapy where one part of the body is isolated for treatment in order to avoid side effects.
LUNG TRANSPLANTATION

XPS & STEEN Solution only FDA (HDE) approved device for warm perfusion of lungs

NOVEL study inclusion finalized:

- **110 + 110 patients**
  - Follow-up 1 year
  - Form basis for PMA application, study documentation & monitoring and analysis ongoing
  - Dialogue with FDA ongoing

- **PAS (Post Approval Study)**
  - 5 patients until inclusion complete
  - Follow-up 3 years

- **Restrictions on patients and recipients will be removed when PAS inclusion finalized**
LUNG TRANSPLANTATION

Next steps for lung warm perfusion (EVLP)

XVIVO will continue to clinically develop EVLP:

- **DCD transplantation (Donation after Circulatory Death)** – controlled / uncontrolled

- **Infection therapy through EVLP**, e.g. Pneumonia therapy and virus reduction – Hep C study: 2 patients included

- Investigate immunological response with EVLP targeting short- & long-term survival

- **New markers and parameters for improved evaluation → safer decision making**
XVIVO - HEART TRANSPLANTATION
Heart perfusion and preservation solution and device developed by Prof. Steen

- **First clinical trial started with new technology:**
  - First patient transplanted with the new device (new solution and new machine)
  - Proof of concept study with 6 patients

- **Pre-clinical porcine proof of concept studies indicate:**
  - Avoidance of ischemic time → Better heart quality
  - Longer preservation time (24h) possible
  - Myocardium tests comparing perfused and non-perfused hearts.

- **Heart Tx very good fit with XVIVO**
  - XVIVO experience from Lung device development
  - Synergies in development, regulatory and M&S
  - Many of the same clinics and KOLs make Heart and Lung Tx

Human hearts kept ‘asleep’ in a box can survive outside the body

Safe orthotopic transplantation of hearts harvested 24 hours after brain death and preserved for 24 hours

Stig Steen, Audrius Paskevicius, Qiuming Liao & Trygve Sjöberg

January – September 2017 Interim report presentation
PRIMECC

Tailor made priming solution aiming at improving patients’ condition after having undergone open-heart surgery with a heart-lung machine

- **PRIMECC®** developed to avoid side-effects when priming heart-lung machines.

- >300 000 open heart surgeries every year in the USA alone. Estimated ~1 million in the world / year.

- No FDA approved product for indication.

- Previous performed clinical “proof of concept” study showed interesting results.

- Patent granted in EU, USA China and Japan.

- CE marked Class III Medical Device.
PRIMECC STUDY INCLUSION FINALIZED

- 40 + 40 patients Sahlgrenska Univ. hosp. - randomized, controlled, blinded

- Aim to increase clinical documentation for PrimECC avoidance of side-effects

- Results estimated to be analyzed & published during Q4 2017 / Q1 2018

- EU & US multi-center studies planned to start after supporting clinical trial results are available
SUMMARY OTHER NEW INDICATIONS

- **Liver transplantation:**
  - Results on 20 patients in first clinical STEEN Solution Liver study show good clinical results
  - Marginal (DCD) Liver study planned to start in Canada on 2 centers

- **Isolated Tissue Therapy - Cancer**
  - Proof of concept study perfusing lungs in vivo for treatment of cancer is ongoing
  - 2nd patient successfully treated
OUTLOOK Q4 2017 & 2018 - FOCUS AREAS

Thoracic Surgery

- Lungs - Continue to increase footprint and use of EVLP technology
- Lungs - PMA application and submission
- Lungs - Reinforced clinical development of EVLP, especially in the US
- Heart - Accelerating Heart transplant clinical program
- PrimECC - Analysis of PrimECC clinical data and continued clinical program

New indications

- Liver - STEEN Solution™ clinical development for DCD & marginal Livers
- ITT - Isolated tissue therapy (STEEN Solution™ IVLP: Cancer, Limb perfusion)
- Kidney – continued pre-clinical studies with STEEN Solution
Strategic goals

- Solidify position in Thoracic surgery - Lungs + Heart
- Build new business using STEEN Solution tech. in other indications
Patients die waiting for an organ transplant

XVIVO has a Patented, Approved and Documented technology to make more organs available for the benefit of patients

XVIVO has the experience, capability, competence and technology to expand into more indications/markets