INTERIM REPORT JANUARY – SEPTEMBER 2018
TELEPHONE CONFERENCE

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

October 26, 2018

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO

NASDAQ OMX Stockholm (mid cap): XVIVO
HIGHLIGHTS JAN – SEP 2018

- PMA application for STEEN Solution ™ and XPS™ submitted to the FDA – dialogue ongoing

- The PrimECC ® study shows that the product is safe and displays positive clinical results – preparation new multicenter study ongoing

- Perfadex Plus has been launched in EU and USA

- United Therapeutics and XVIVO Perfusion initiated collaboration on EVLP

- The heart preservation machine has been successfully tested with porcine hearts during 24 h – multicenter study preparation ongoing
SALES HIGHLIGHTS JAN – SEP 2018

- Net Sales all products Jan - Sep grew +21% (+19% in local curr.) to 129.5 MSEK.

- Net Sales non-durable goods Jan - Sep grew +19% (+16% in local curr.) to 120.4 MSEK.

- Continued strong growth for non-durable Warm perfusion sales:
  - Q3 alone growth + 65% (YoY)
  - 12 month rolling growth +42% (YoY)
## PROFIT & LOSS

<table>
<thead>
<tr>
<th>(SEK Millions)</th>
<th>2018 Jan-Sep</th>
<th>2017 Jan-Sep</th>
<th>2017 Whole year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>129.5</td>
<td>106.8</td>
<td>148.3</td>
</tr>
<tr>
<td><strong>Net sales non-Durable goods</strong></td>
<td>120.4</td>
<td>101.6</td>
<td>141.0</td>
</tr>
<tr>
<td>Gross profit</td>
<td>94.2</td>
<td>81.6</td>
<td>113.4</td>
</tr>
<tr>
<td>Gross Margin %</td>
<td>73%</td>
<td>76%</td>
<td>76%</td>
</tr>
<tr>
<td>Gross Margin non-Durable goods %</td>
<td>77%</td>
<td>79%</td>
<td>78%</td>
</tr>
<tr>
<td>Selling expenses excl. items eff. comp%</td>
<td>-26%</td>
<td>-31%</td>
<td>-29%</td>
</tr>
<tr>
<td>Admin. expenses excl. items eff. comp%*</td>
<td>-11%</td>
<td>-13%</td>
<td>-13%</td>
</tr>
<tr>
<td>R&amp;D exp. excl. Amort. &amp; items eff. comp%*</td>
<td>-21%</td>
<td>-19%</td>
<td>-18%</td>
</tr>
<tr>
<td>Items effecting comparability*</td>
<td>0%</td>
<td>-2%</td>
<td>-2%</td>
</tr>
<tr>
<td>R&amp;D Amortization %*</td>
<td>-6%</td>
<td>-7%</td>
<td>-7%</td>
</tr>
<tr>
<td>Other income/expenses %</td>
<td>-2%</td>
<td>-2%</td>
<td>-2%</td>
</tr>
<tr>
<td>Operating Result %</td>
<td>6%</td>
<td>2%</td>
<td>5%</td>
</tr>
<tr>
<td><strong>EBITDA excl. items eff. comp.</strong></td>
<td>20.4</td>
<td>15.7</td>
<td>24.8</td>
</tr>
<tr>
<td>EBITDA excl. items eff. comp%</td>
<td>16%</td>
<td>15%</td>
<td>17%</td>
</tr>
<tr>
<td>EBITDA</td>
<td>20.4</td>
<td>13.4</td>
<td>22.0</td>
</tr>
<tr>
<td>EBITDA %</td>
<td>16%</td>
<td>13%</td>
<td>15%</td>
</tr>
</tbody>
</table>

**Non-durable Sales +19%**

**Customer support build up continued, cost % lower due to vacancies start of year (now filled)**

**Cost effected by 3.8 MSEK from US share based bonus (mirror of Swedish Warrant program) included**

**Lung Tx business profitable despite high investments in Marketing and R&D**

Items effecting comparability: 0.0 (2.3) MSEK. R&D Amortization: 8.2 (7.9) MSEK.
PERFADEX PLUS LAUNCH
A ready to use Perfadex with increased patient safety and customer convenience

- Upgraded ready to use version of Perfadex
- CE marked and FDA (510k) registered
- Patent application filed
- Launched in Europe and USA (Sep 2018)
- Launch in other markets planned within 12 months
PRODUCTS & MARKETS FOR FUTURE GROWTH
XVIVO - FUTURE GROWTH OPPORTUNITIES

Expansion of Lung transplantation indication, EVLP improvement projects, increase of DCD

Heart Transplant project, early clinical phase

STEEN Solution™ for Liver Transplant, early clinical phase

PrimECC improve clinical proof, late clinical phase

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

NOVEL study & Post Approval Study (PAS):

- PMA study 110 + 110 patients included
- PMA application submission
- Dialog with FDA regarding application ongoing

- PAS (Post Approval Study)
  - 126 + 126 inclusion completed
  - Follow-up 3 years (May 2020)

- Restrictions on patients and recipients removed since PAS inclusion finalized

- CPT codes for EVLP active → Enables reimbursement of clinical team’s time for EVLP
LUNG TRANSPLANTATION
Next steps for lung warm perfusion (EVLP)

XVIVO will continue to clinically develop EVLP:

- Use of DCD* lungs for transplantation
  - controlled / uncontrolled

- Ex Vivo Infection therapy through EVLP e.g. Pneumonia therapy and virus reduction
  - 20 Hep C infected lungs transplanted

- Investigate immunological response during EVLP targeting short term organ function & long term survival

- Continued development of the XPS to enable online parameters for better decision making, e.g. weight change

*Donation after Circulatory Death
Heart Transplantation device:

- Transportable Machine & organ adapted Solution to enable longer preservation time and keep heart in better condition before transplantation
- Device approved for air transportation

Pre-clinical proof of concept studies indicate:

- No non-oxygenated time → Better organ quality
- Longer preservation time possible (24h in pigs)
Clinical development with new technology:

- Safety study on 6 patients ongoing

- Preparations ongoing for multicenter studies in EU and the US:
  - Production development of heart perfusion solution & heart disposable kit started
  - All participating clinics trained on heart transplant device at Igelösa Research center.
PRIMECC® developed to avoid side-effects when priming heart-lung machines:

- Patent granted in EU, USA, China & Japan
- CE marked Class III Medical Device
- Clin. Study with 40+40 patients completed

Result from analysis of Clinical study:

- PrimECC® is safe to use
- Improved fluid balance and reduction of side effects using a heart-lung machine primed with PrimECC®
PRIMECC – MULTICENTER STUDY PLANNED

Continued clinical documentation

Main focus to start multicenter study in end 2018 / beg. 2019

- Good response from clinics that will participate in multicenter study
- Multicenter study to focus on findings from Sahlgrenska clinical study but with higher number of patients
OUTLOOK 2018 - FOCUS AREAS

Thoracic Transplantation / Surgery

- Lungs – Continue to increase footprint and support use of EVLP technology
- Lungs – Reinforced clinical development of EVLP, e.g. DCD usage trial
- Lungs – Hepatitis C infected donors study ongoing
- Heart – Accelerating Heart transplant project – multicenter trial planned Q1, 2019
- PrimECC – Clinical documentation – multicenter trial planned Q4 2018 / Q1 2019

Abdominal Transplantation & new indications

- Liver – STEEN Solution™ clinical development for Liver Tx
- Kidney – continued pre-clinical studies with STEEN Solution
- ITT – Isolated tissue therapy (Cancer / STEEN Solution™ IVLP)

→ Long-term goal is to solidify position in Thoracic surgery and build a new business using the STEEN Solution technology in abdominal transplantation and 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