INTERIM REPORT JANUARY – DECEMBER 2018

TELEPHONE CONFERENCE

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

February 8, 2019

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO
HIGHLIGHTS Q4 – RECORD SALES QUARTER

• All time high sales and record growth
  - Net Sales all products Oct - Dec grew +40% (+33% in local curr.) to 58 MSEK.
  - Net Sales non-durable goods Oct - Dec grew +33% (+26% in local curr.) to 52 MSEK, which was all time high.

• Warm sales non-durable portion 50% for the first time
  - Warm growth + 54% (YoY)

![Warm Perfusion Sales from non-durable goods, in SEK millions (Rolling 12 months)]
HIGHLIGHTS JAN – DEC 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

• 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 – DEC 2018

• **Net Sales all products Jan - Dec** grew +27% (+23% in local curr.) to 188 MSEK.

• **Net Sales non-durable goods Jan - Dec** grew +22% (+19% in local curr.) to 173 MSEK.

• **Continued strong growth for non-durable Warm perfusion sales**, with 12 month rolling growth +48% (YoY)
## PROFIT & LOSS

<table>
<thead>
<tr>
<th>(SEK Millions)</th>
<th>2018 Jan-Dec</th>
<th>2017 Jan-Dec</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>187.9</td>
<td>148.3</td>
</tr>
<tr>
<td>Net sales non-Durable goods</td>
<td>172.7</td>
<td>141.0</td>
</tr>
<tr>
<td>Gross profit</td>
<td>136.0</td>
<td>113.4</td>
</tr>
<tr>
<td>Gross Margin %</td>
<td>72%</td>
<td>76%</td>
</tr>
<tr>
<td>Gross Margin non-Durable goods %</td>
<td>77%</td>
<td>78%</td>
</tr>
<tr>
<td>Selling expenses * %</td>
<td>-26%</td>
<td>-29%</td>
</tr>
<tr>
<td>Admin. expenses * %</td>
<td>-12%</td>
<td>-13%</td>
</tr>
<tr>
<td>R&amp;D exp. excl. Amort. * %</td>
<td>-20%</td>
<td>-18%</td>
</tr>
<tr>
<td>Items effecting comparability * %</td>
<td>0%</td>
<td>-2%</td>
</tr>
<tr>
<td>R&amp;D Amortization ** %</td>
<td>-6%</td>
<td>-7%</td>
</tr>
<tr>
<td>Other income/expenses %</td>
<td>-2%</td>
<td>-2%</td>
</tr>
<tr>
<td>Operating Result %</td>
<td>7%</td>
<td>5%</td>
</tr>
<tr>
<td>EBITDA excl. items effecting comparability</td>
<td>30.9</td>
<td>24.8</td>
</tr>
<tr>
<td>EBITDA excl. items effecting comparability %</td>
<td>16%</td>
<td>17%</td>
</tr>
<tr>
<td>EBITDA</td>
<td>30.9</td>
<td>22.0</td>
</tr>
<tr>
<td>EBITDA %</td>
<td>16%</td>
<td>15%</td>
</tr>
</tbody>
</table>

**Non-durable Sales +22%**

**Continued high Gross Margin**

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

**R&D clinical and product development build up**

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

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*Excluding items effecting comparability: 0.0 (2.8) MSEK.
**R&D Amortization: 10.9 (10.6) MSEK.
ACCOMPLISHMENTS OF 2018 & NEXT STEPS IN LUNG TRANSPLANTATION
PERFADEX® PLUS LAUNCH
A ready to use Perfadex® with increased patient safety and customer convenience

- Successfully launched in Europe and USA
- Well received by customers and clinicians
  - Ready to use and click port – reduced complexity and preparation time while increasing patient safety
- Patent applications filed
- Plan for 2019 - launch in all other markets after regulatory approval
LUNG TRANSPLANTATION
WARM PERFUSION - INCREASED FOOTPRINT

- Collaboration between United Therapeutics and XVIVO Perfusion initiated, with 2 XPS™ sold.
- 8 new XPS™ and LS™ machines on the market
- Three more Technical Advisors added to the team
- Established Global Marketing department
- Established Operations team for broader product line

Number of EVLPs increased
• CPT* Reimbursement codes obtained for doctor’s time during EVLP procedure in US

• PMA application for STEEN Solution™ and XPS™ submitted to the FDA

• Continued development of the XPS™ to enable online parameters for better decision making
  - XVIVO Monitoring and Analysis Tool (XMAT)
  - Online weight sensor
  - Online CO₂ sensor

Number of EVLPs increased

* CPT = Current Procedural Terminology
XPS™ and LS™ FOOTPRINT

49 hospitals have access to either XPS™ or LS™
LUNG TRANSPLANTATION
NEXT STEPS FOR WARM LUNG PERFUSION (EVLP)

• Broaden EVLP indications
  o Use of DCD* lungs for transplantation
  o Anti-Infection therapy through EVLP e.g. pneumonia therapy and virus reduction (+20 Hep C lungs transplanted)
  o Immunological response during EVLP

• Improve ease of use
  o Protocol development
  o XPS™ automated steps in set-up and control
  o Clinical online parameter trending to improve decision making

*Donation after Circulatory Death
PRODUCTS & MARKETS FOR FUTURE GROWTH
Heart Transplant project, optimized preservation to prolong time outside the body.

PrimECC®, optimized priming solution to reduce known side effects.

STEEEN Solution™ for Liver and Kidney Transplant, evaluation of marginal and DCD organs.

ITT* - Perfusion of isolated organs / tissues (e.g. Drug administration) with STEEN Solution™

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

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

Stig Steen, Audrius Paskevicius, Qiuming Liao & Trygve Sjöberg
XVIVO - HEART TRANSPLANTATION
ACCOMPLISHMENTS 2018

• New clinical trial version machine rollout
• Machine and Solution successfully tested on pig heart for 24 hours with great results
• Clinical multi center study preparation
  o Clinical protocol developed
  o Trial participants trained at Igelösa
  o Machine, Disposables, and Solutions production set up
  o Application submitted to the Swedish Medical Products Agency
PrIMECC®

Accomplishments

• Patented
• CE marked
• Clinical study with 40+40 patients showed
  o PrimECC® is safe to use
  o Improved fluid balance and reduction of side effects using a heart-lung machine primed with PrimECC®

Next steps

• Set up a large scale production in eco friendly bags
• Clinical study on sub groups
  o Good response from clinics that will participate in multicenter study
  o Multicenter study to focus on findings from Sahlgrenska clinical study but with higher number of patients

Development stage: Late Clinical Phase

Serval hundred thousand operations using a heart-lung machine are performed each year. PrimECC® is developed to prime the heart-lung machine before open heart surgery.
Main Focus

Thoracic Transplantation / Surgery
- Lungs – Continue to increase footprint and support use of EVLP technology
- Heart – Preparation for multicenter study for regulatory approval
- PrimECC® – Preparation for multicenter study for clinical documentation

Secondary Focus

Abdominal Transplantation & new indications
- Liver with STEEN Solution™ - continued support for further development.
- 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
→ 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