

30TH QUARTERLY REPORT

INTERIM REPORT

JAN – MAR 2020

TELEPHONE CONFERENCE
APRIL 9th, 2020

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO

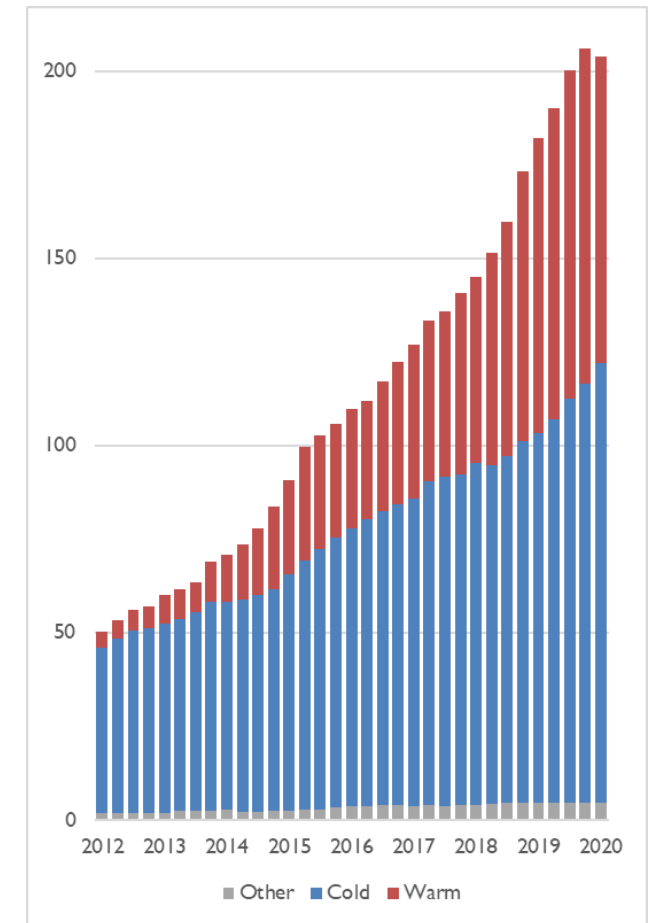


HIGHLIGHTS Q1 - STRONG CASH POSITION

- Very limited cash consumption during Q1 in spite of heavy investment in R&D and XVIVO ends the quarter in a good financial position:
 - ▶ 159 MSEK at end Q1 v. 160 MSEK at end Q4 2019
- Net sales -2.5% in SEK (-6% in LC*)
 - ▶ Non-durable sales -6% in SEK
 - ▶ Strong growth of cold sales +22% in SEK
- Strong gross margin, 79%, of non-durable goods
- Good profit level – EBITDA 16%
- XPS™ sold to pediatric transplantation clinic in Italy
- Launch in Europe/ROW of the upgraded ready-to-use Perfadex Plus – with click adaptor

* Local currency

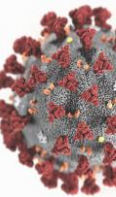
Net Non-durable Sales
(rolling 12 months)



THE COVID-19 EFFECT ON XVIVO PERFUSION

XVIVO Perfusion sees no reason why COVID-19 pandemic should affect long-term demand of XVIVO's products

- ▶ XVIVO is implementing a **temporary cost reduction program** to reduce expenditure to a substantially lower level
- ▶ Clinical studies are delayed but XVIVO focuses on being prepared to start these trials as soon as it will be possible



XPS™ SOLD TO PEDIATRIC TRANSPLANTATION CLINIC IN ROME, ITALY

- The first XPS™ to a pediatric hospital
- The clinic is situated in Rome, Italy – a sign that the transplant community even in Italy already plans for the situation post-Corona virus epidemic
- Opens up to be able to expand the use of donated lungs for transplantation for children and adolescents with terminal lung diseases



THE UPGRADED, READY TO USE PERFADEX® PLUS W/ CLICK ADAPTER LAUNCHED IN EUROPE & CANADA

- PERFADEX® Plus with Click Adapter has been launched in Europe and Canada after clearance from notified body and regulatory authority, respectively
- This version of ready-to-use PERFADEX® increase patient safety and customer convenience through easier use “in the field”
- PERFADEX® Plus with Click Adapter has previously only been launched in USA – and was very well received by the clinics there
- PERFADEX® Plus is patented in Europe and patent applications are pending in all other major markets



PROFIT & LOSS

Net sales close to Q1 2019

Continued high Gross Margin

Continued customer support build up

Continued ambitious R&D investment

Lung Tx business profitable with continued investments in Marketing and R&D.

| (SEK Millions) | 2020 Jan - Mar | 2019 Jan - Mar | 2019 Full year |
|---------------------------------------------------|-------------------|-------------------|-------------------|
| Net sales | 46.5 | 47.6 | 220.8 |
| Net sales non-Durable goods | 44.2 | 46.8 | 206.9 |
| Gross profit | 35.4 | 36.9 | 162.8 |
| Gross Margin % | 76% | 77% | 74% |
| Gross Margin non-Durable goods % | 79% | 77% | 77% |
| Selling expenses % | -32% | -25% | -28% |
| Admin. expenses % | -12% | -11% | -11% |
| R&D exp. excl. Amort. ** % | -25% | -25% | -21% |
| Items effecting comp. * % | 5% | -12% | -3% |
| R&D Amortization ** % | -11% | -6% | -8% |
| Other expenses excl. Items effecting comp. * % | -1% | -13% | -2% |
| Operating Result % | 0% | -4% | 2% |
| EBITDA excl. items effecting comperability | 5.0 | 8.8 | 35.8 |
| EBITDA excl. items effecting comperability | 11% | 18% | 16% |
| EBITDA | 7.6 | 3.2 | 28.8 |
| EBITDA % | 16% | 7% | 13% |

* Items effecting comparability: 2.5 (-5.5) MSEK

** R&D Amortization: -5.0 (-3.0) MSEK

Items effecting comparability are +2.5 MSEK due to the decreased share price. The AGM 2017-2019 approved a sharebased bonus program to employees outside Sweden, mirroring the Swedish warrant program.

GOOD CASH FLOW – STRONG CASH POSITION

- In spite of continued ambitious cash investments of 27 MSEK in R&D, the net cash position remained almost intact during the quarter
- In the latter part of Q1 a cost reduction program was initiated which contributed to a strong operating cash flow
- XVIVO Perfusion net cash position continues to be strong in absolute terms:
159 MSEK at end of Q1 2020 (v. 160 MSEK at start of quarter)

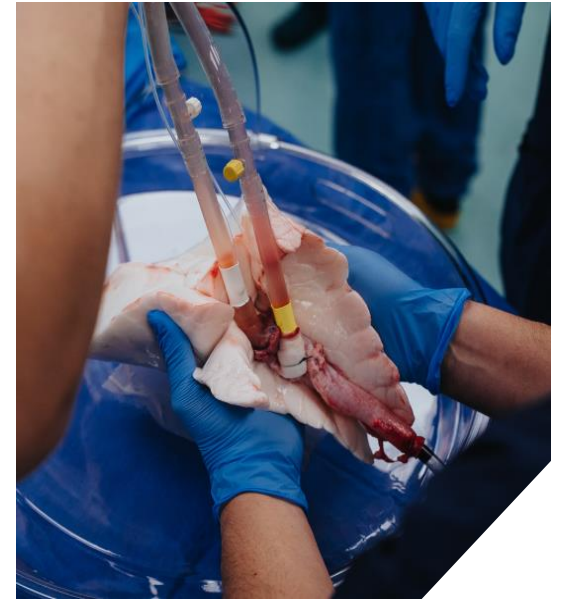




THE R&D PIPELINE - TO ENSURE FUTURE GROWTH

XVIVO ENABLE FUTURE GROWTH WITHIN LUNG TRANSPLANTATION

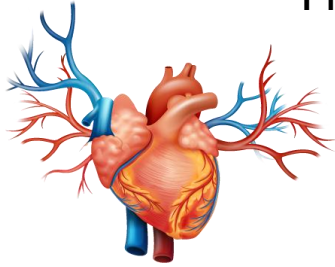
- **Continued XPS development of online parameters improving decision making**
 - ▶ Sensors for weight, blood gases, metabolites etc., Biomarkers for organ viability
 - ▶ Easy of use, automatizations, remote monitoring
- **Solution research to further strengthen organ enduringness and to prolong possible time of EVLP**
 - ▶ New additives to further mimic physiology
- **Expanded use of DCD* lungs for transplantation**
 - ▶ Clinical research on Controlled/Uncontrolled DCD
- **Continued EVLP protocol development**
 - ▶ Ventilation strategy, organ in prone position etc.
- **Investigating immunological response during EVLP**
 - ▶ Targeting short term organ function & long-term survival



* DCD - Donation after Circulatory Death

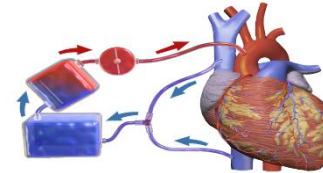
XVIVO – THE R&D PIPELINE

Priority 1



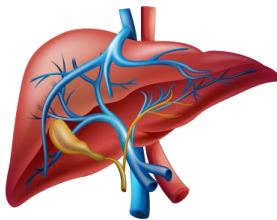
Heart Transplant project, optimized preservation to sustain organ quality

Priority 2



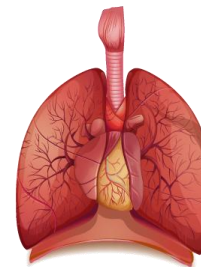
PrimECC®, optimized priming solution to reduce known side effects

Priority 3



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

Priority 4



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

* ITT - Isolated Tissue Therapy

XVIVO - HEART TRANSPLANTATION

Development stage:
Early Clinical Phase

HEART PERFUSION AND PRESERVATION SOLUTION AND DEVICE DEVELOPED BY PROF. STEEN

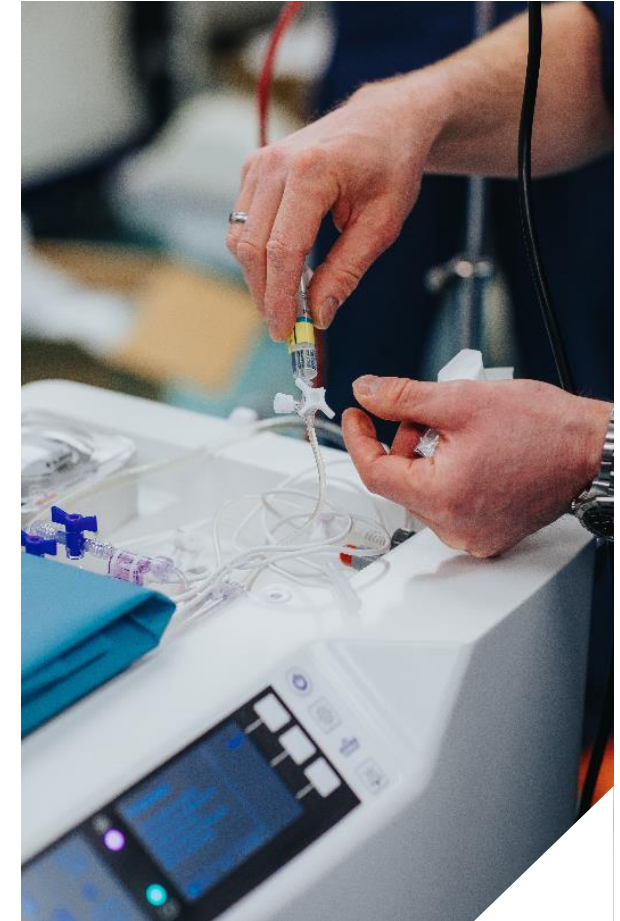
- Pre-clinical proof of concept studies indicate:
 - ▶ No non-oxygenated time (NIHP*) → Better organ quality
 - ▶ Longer preservation time possible (24h in pigs)
 - ▶ In the sensitive Pig to Monkey Xeno-transplant it facilitated a 6 month survival study (first in the world)
- The ongoing clinical study at Lund University Hospital with result on first 9 patients after 6 months indicate:
 - ▶ Hearts can be safely preserved with Prof. Steen's NIHP* technology resulting in successful transplantation
 - ▶ Reduced risk for ischemic induced reperfusion injury



* NIHP - Non-Ischemic Heart Preservation

XVIVO - HEART TRANSPLANTATION - ACCOMPLISHMENTS

- ▶ Patents for the heart preservation fluid approved in the US, Canada & Europe
- ▶ Clinical team build-up, machine, disposables and solution design finalized, tested and production validated and ramped up
- ▶ Ongoing preparations for multi-center trials in Europe, US and Australia – clinics recruited and being prepared for study start
- ▶ XVIVO Heart Preservation System (XHPS) has been granted 'Breakthrough Device Designation' from the FDA – shortening time to market
- ▶ The European multi-center trial was ready to include first patient in QI, but is on hold due to COVID-19 pandemic outbreak - New starting dates will be defined based on how the situation develops in each country and clinic



PRIMECC® - BACKGROUND

Development stage:
Late Clinical Phase

- Priming solutions are used to prepare the heart-lung machines before employed in open heart surgery. These solutions enter the patients' bloodstream at the start of the procedure to replace the blood volume filling the H-L machine.
 - ▶ The solutions used today are not regulatory approved, not optimized and are known to cause side-effects
 - ▶ 600-700 thousand procedures (=bags) are used each year when running heart-lung machines in open heart surgery
 - ▶ PrimECC® is developed to alleviate well known side effects



PRIMECC® - DEVELOPMENT STATUS

Development stage:
Late Clinical Phase

Accomplishments

- Patented in EU, USA, China and Japan
- CE marked
- Clinical study in 40 + 40 patients at Sahlgrenska Univ. Hospital showed
 - ▶ PrimECC® is safe to use
 - ▶ Improved fluid balance and reduction of side effects using a heart-lung machine primed with PrimECC®
- Production of 1st validation batch in eco friendly bags with satisfying result
- Regulatory file for new production site and packaging has approved by the Notified Body
- Ethical committee has approved to start the trial

Ongoing

- Preparations are done to start the clinical multi-center trial
 - ▶ Multi-center trial at Swedish hospitals was ready to include the first patient but has been postponed due to COVID-19 pandemic outbreak.
 - ▶ The company is ready to start the clinical trial as soon as the situation at the hospitals so permit.

OUTLOOK 2020 - FOCUS AREAS

- During the COVID-19 situation
 - ▶ XVIVO is implementing a temporary cost reduction program to bring expenditure to a substantially lower level
 - ▶ Clinical studies are delayed but XVIVO focuses on being prepared to start these trials as soon as it will be possible
- Thoracic Transplantation / Surgery (Primary focus)
 - ▶ Lungs – Further support development of EVLP technology and clinical practice
 - ▶ Heart – Start and run multi-center studies for regulatory approval in all major markets
 - ▶ PrimECC® – Start and run multi-center study for clinical documentation
- Abdominal Transplantation & new indications (Secondary focus)
 - ▶ Continued support for clinical development of Liver Tx and Kidney Tx with STEEN Solution™ technology
 - ▶ Future investigation of how to employ XVIVO technology into abdominal organs
- Long-term goals
 - ▶ Solidify position in Thorax surgery (Lung Tx, Heart Tx, PrimECC®)
 - ▶ Build a new business using the STEEN Solution™ technology in Liver and Kidney Tx



OUR VISION:
**NOBODY SHOULD
DIE WAITING FOR
A NEW ORGAN**