

31TH QUARTERLY REPORT

INTERIM REPORT

JAN – JUN 2020

TELEPHONE CONFERENCE
July 10th, 2020

DAG ANDERSSON, CEO
CHRISTOFFER ROSENBLAD, CFO

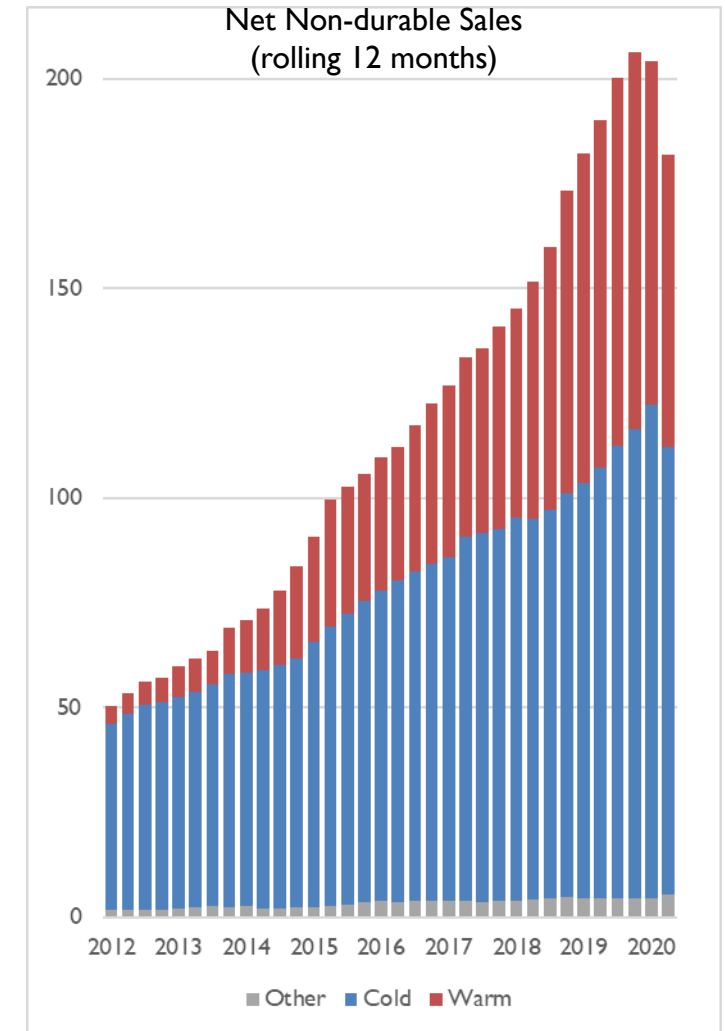


HIGHLIGHTS H1

- Net sales -28% in SEK (-26% in LC¹)
 - ▶ Consumable sales² -28% in SEK
- Strong gross margin Consumable sales of 80%
- Positive profit level – EBITDA excl. one time cost 5%
- Positive cashflow from operating activities in Q1 and Q2
- 2 lung evaluation machines sold in Europe
 - ▶ 6 upgrades to newest version of the machine
- Activity increasing after significant dip during March - May
 - ▶ Lack of ICU capacity during COVID-19 impacting donor programs
- COVID-19 patients have been transplanted in US, Europe and Asia
- Successful launch of PERFADEX[®] Plus with Click Port in Europe and Canada. Full implementation completed

¹ Local currency

² Including sales from fluids, kits, freight and service



PROFIT & LOSS

Continued high Gross Margin

Cost reduction program enforced during Q2 due to COVID-19

Continued high investments into prioritized projects within Commercial and R&D

(SEK Millions)	2020 Jan-Jun	2019 Jan-Jun	2019 Full year
Net sales	76.8	104.1	220.8
Net sales non-Durable goods	72.2	97.3	206.9
Gross profit	58.5	78.6	162.8
Gross Margin %	76%	75%	74%
Gross Margin non-Durable goods %	80%	77%	77%
Selling expenses %	-35%	-27%	-28%
Admin. expenses %	-14%	-11%	-11%
R&D exp. excl. Amort. ** %	-25%	-20%	-21%
Items affecting comp. * %	-3%	-9%	-3%
R&D Amortization ** %	-13%	-7%	-8%
Other expenses excl. Items affecting comp. * %	-3%	-11%	-2%
Operating Result %	-17%	0%	2%
Operating Result * %	-14%	9%	5%
EBITDA excl. items affecting comparability	4.1	20.8	35.8
EBITDA excl. items affecting comparability %	5%	20%	16%
EBITDA	2.1	11.3	28.8
EBITDA %	3%	11%	13%

Items affecting comparability are -2.0 MSEK due to reorganization cost of -4.5 MSEK and +2.5 MSEK resolution of cost provisions for share-based bonus programs for employees outside Sweden

* Items affecting comparability: -2.0 (-9.5) MSEK

** R&D Amortization: -10.0 (-7.2) MSEK

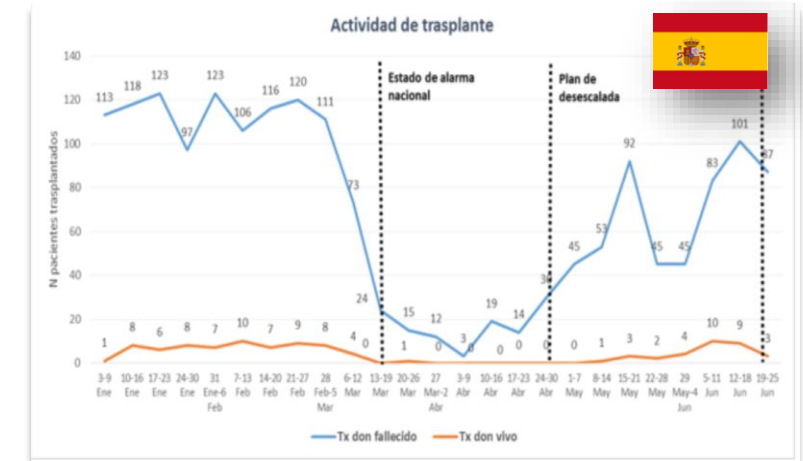
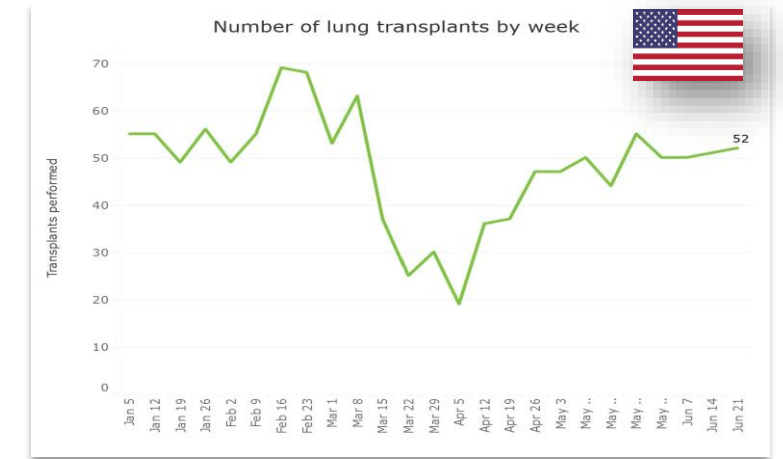
COVID-19 IMPACT ON TRANSPLANT ACTIVITY

MARCH – APRIL:

- An increase in COVID-19 infections resulted in a significant reduction in overall organ transplantation procedures globally

MAY – JUNE

- LTx activity in US is starting to get back to normal levels again
 - ▶ No of LTx 1257 (2019) vs 1180 (2020), -6%
- Increased LTx activity also in Europe the last month, but slightly slower than US



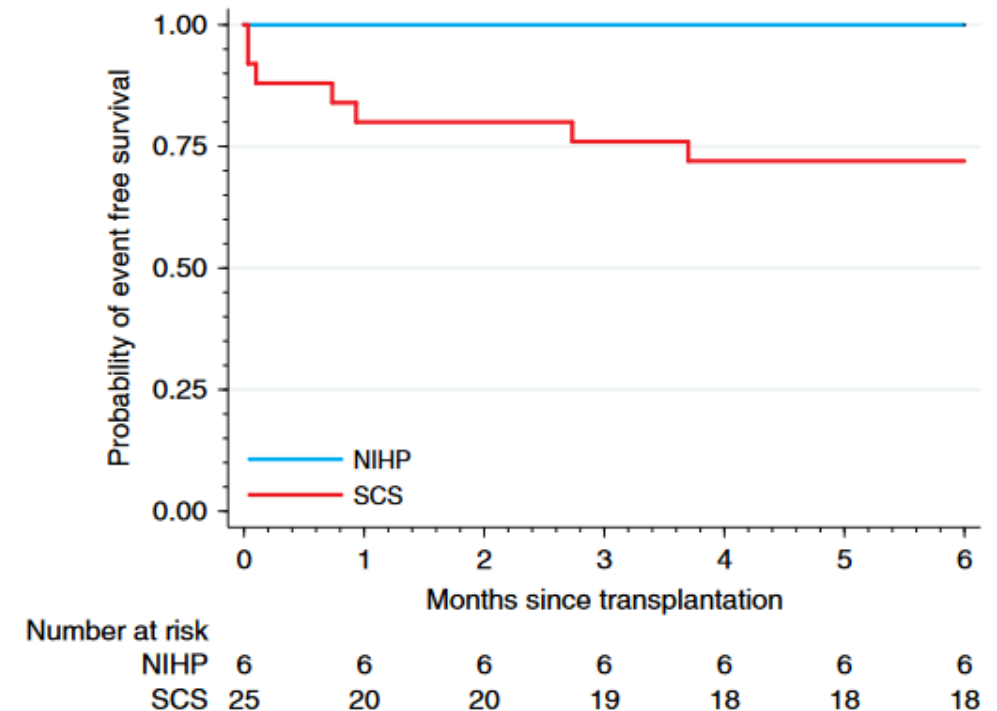
TWO LUNG EVALUATION MACHINES SOLD IN EUROPE

- **Sold to a leading lung transplant clinic in Vienna, Austria**
 - ▶ A high volume lung transplant center with more than 100 transplantations per year
 - ▶ The clinic has set up an EVLP (Ex Vivo Lung Perfusion) program in record time and performed lung evaluations using our XPS™ machine and our solutions
 - ▶ AKH in Vienna is a prominent clinic that during the quarter also performed a transplant of a patient whose lungs were destroyed by a COVID-19 infection
- **Sold to pediatric transplantation clinic in Rome, Italy**
 - ▶ The first XPS™ to a pediatric hospital
 - ▶ Opens up to be able to expand the use of donated lungs for transplantation for children and adolescents with terminal lung diseases



THE STUDY FROM LUND PUBLISHED IN NATURE COMMUNICATIONS

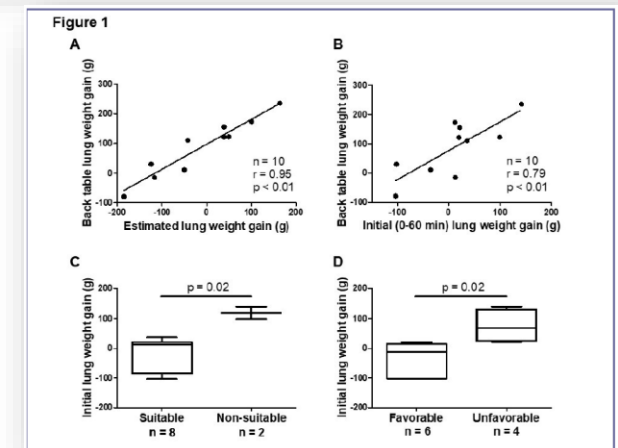
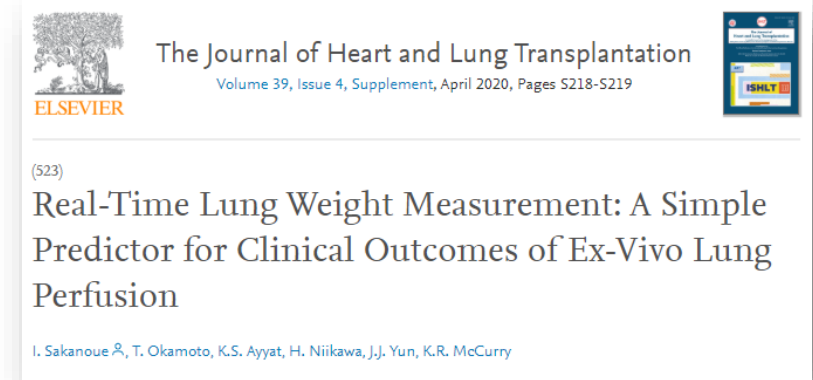
- First scientific publication with clinical transplantation after use of prof Steen's NIHP* method
- Six patients followed for 6 months after NIHP transplant with 100% survival free from major complications or rejection of the new heart
- Control group: Standard Cool Storage (SCS)



* NIHP - Non-Ischemic Heart Preservation

WEIGHT SENSOR STUDY FROM CLEVELAND CLINIC PUBLISHED IN THE JOURNAL OF HEART LUNG TRANSPLANTATION

- Previously lung weight could only be taken at the beginning and end of EVLP without any knowledge to when weight changes occurred
- The value of knowing the overall weight gain following EVLP was subject to some debate
 - ▶ The article explains that weight gains that occurs in the beginning stages of perfusion are indicative of the lung health
 - ▶ This is important because it allows XPS™ users to have an additional parameter for their critical decision as whether to transplant or not
 - ▶ Additionally, in the future this may allow for a quicker evaluation protocol



XVIVO WEBINARS

- **XVIVO has hosted a series of five webinars addressing:**
 - ▶ The impact of the COVID-19 pandemic on transplant centers and organ procurement organizations around the world
 - ▶ Top KOLs in the lung transplant field have moderated and presented at the different webinars sharing their experiences from clinics around the world
 - ▶ In total ~ 500 registered and ~350 participants
 - ▶ Very positive feedback received from participants attending the webinars
- **Upcoming webinars will be held 1-2 times per quarter covering various topics around transplantation**

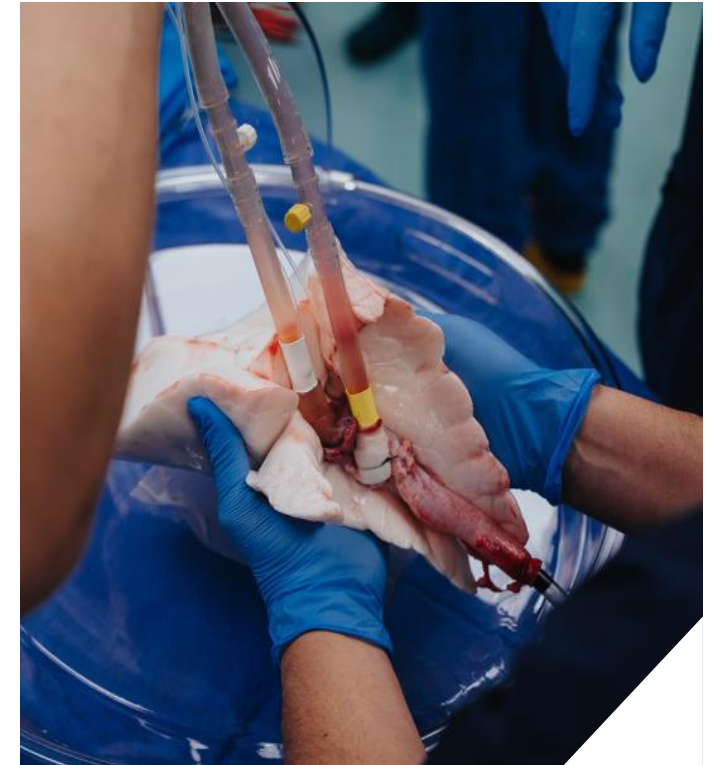




THE R&D PIPELINE - TO ENSURE FUTURE GROWTH

XVIVO SECURING CONTINUED GROWTH WITHIN LUNG TRANSPLANTATION

- **Continued EVLP protocol development**
 - ▶ Ventilation strategy, organ in prone position etc.
- **Machine strategy: increasing options for customers**
 - ▶ Easy of use and flexible protocols
 - ▶ Adding sensors for weight, blood gases, metabolites etc.
 - ▶ Validation of biomarkers for organ viability
- **Next generation EVLP fluid**
 - ▶ To further increase usage rate of lungs
- **Expanded use of DCD (Donation after Circulatory Death) lungs for transplantation**
 - ▶ Clinical research on Controlled/Uncontrolled DCD

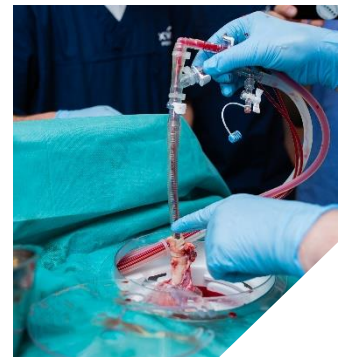
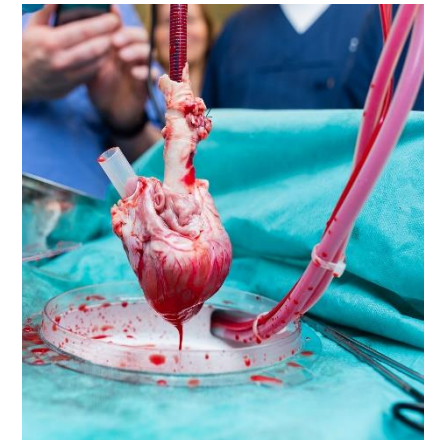
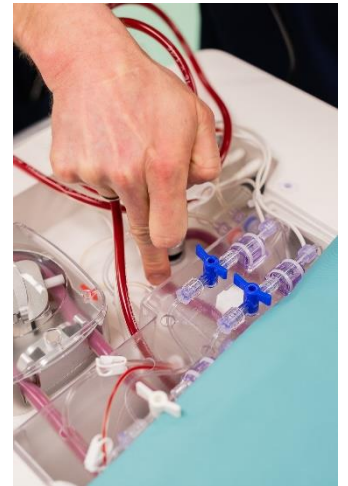


XVIVO - HEART TRANSPLANTATION

HEART PRESERVATION SOLUTION AND DEVICE DEVELOPED BY PROF. STEEN

Development stage:
Early Clinical Phase

- **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 and published in Nature)
- **The ongoing clinical study at Lund University Hospital with result on first 6 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
 - ▶ Publication in Nature: Six patients followed for 6 months after NIHP transplant with 100% survival free from major complications or rejection of the new heart

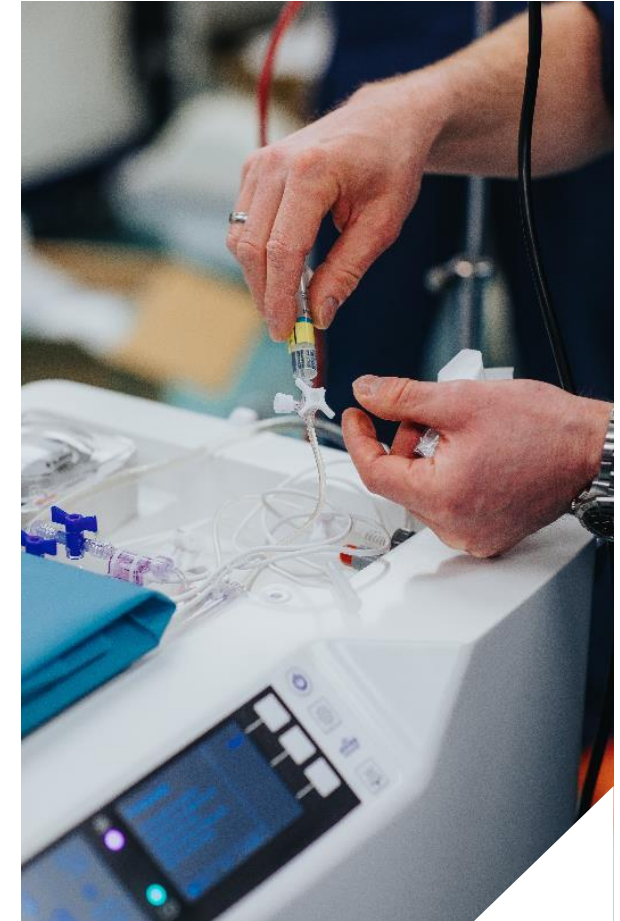


* NIHP - Non-Ischemic Heart Preservation

XVIVO - HEART TRANSPLANTATION - ACCOMPLISHMENTS

Development stage:
Early Clinical Phase

- Patents for the heart preservation fluid approved in the US, Canada & Europe
- Clinical team build-up, machine, disposables and solution design finalized, tested, production validated and ramped up
- Ongoing preparations for multi-center trials in Europe, US and Australia
 - ▶ Belgium, France and Germany ready to start study
- XVIVO Heart Preservation System (XHPS) was granted 'Breakthrough Device Designation' from the FDA – planned IDE submission in Q3



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 heart-lung 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 40+40 patients at Sahlgrenska University 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 approval to start the trial

ONGOING

- Preparations are done to start the clinical multi-center trial
 - ▶ Multi-center trial at Swedish hospitals is ready to include the first patient.
 - ▶ The trial is planned to start in Q3 at Sahlgrenska followed by 2-3 additional trial sites during 2020.

OUTLOOK 2020 – FOCUS AREAS

- **Thoracic Transplantation / Surgery**

- ▶ 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

- **Long-term goals**

- ▶ Solidify position in Thorax surgery (Lung Tx, Heart Tx, PrimECC®)
- ▶ To enter the liver and kidney organ segment

- **During the COVID-19 situation**

- ▶ XVIVO has implemented a temporary cost reduction program to bring expenditure to a lower level
- ▶ Clinical studies are ready to start



CEO COMMENTS AFTER FIRST MONTH

- To support the clinical development forward a Chief Intellectual Property Officer and a Chief Medical Officer have been appointed
- The organization will be further strengthened during the early autumn with a Head of Commercial and a Head of R&D
- Focus on further commercializing the organization (sales force, pricing, tools), improving project management and time to market
- Clear prioritization – focus on “Top 5 priorities” for company and functions





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