

INTERIM REPORT JANUARY – MARCH 2017 TELEPHONE CONFERENCE

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

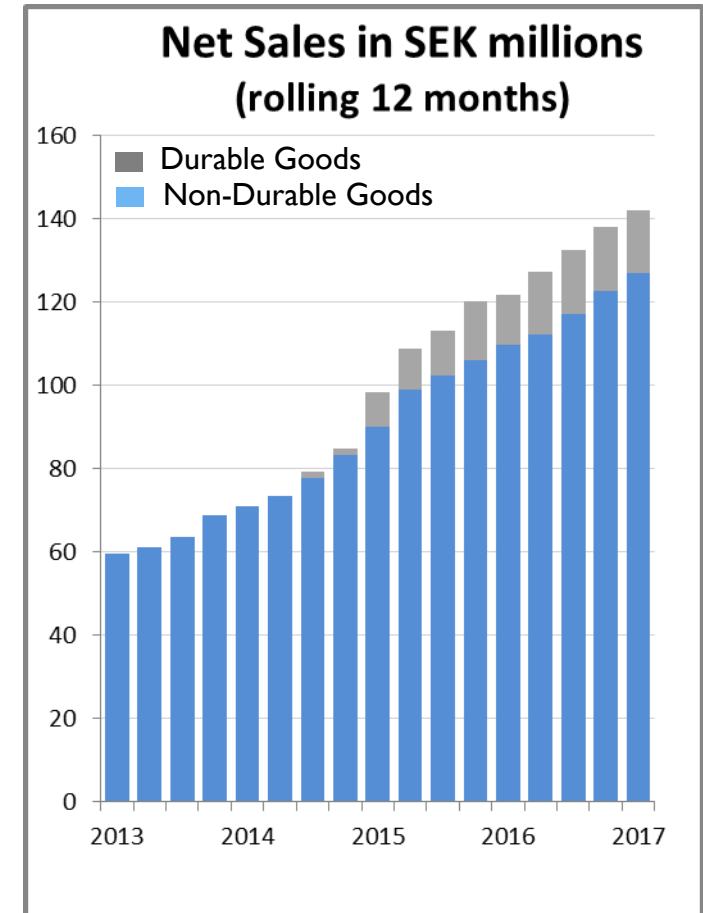
April 25, 2017

MAGNUS NILSSON, CEO
CHRISTOFFER ROSENBLAD, CFO

HIGHLIGHTS 2017-Q1

- **Q1 sales +12%, 37.5 MSEK**
- **2 new countries with XPS**
 - **Australia & the Netherlands**
- **Directed issue of 181 MSEK**
 - **To faster develop Heart transplant portfolio**
 - **AP4, Norron, Swedbank & AP3 participated**
- **Heart Transplant team established in Lund, Sweden**

Net sales



SALES HIGHLIGHTS 2017-Q1

DOUBLE DIGIT GROWTH

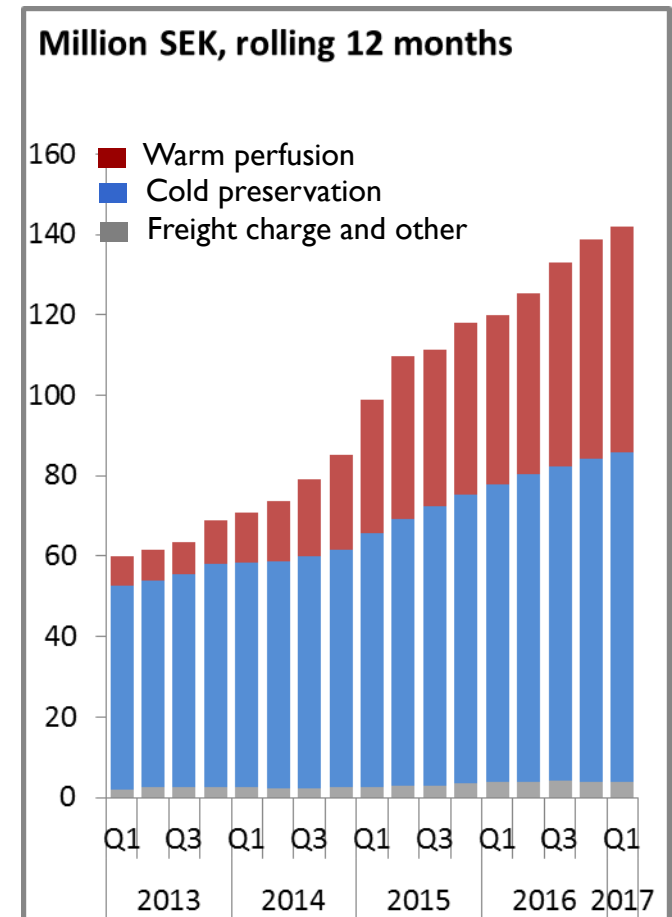
- **Sales:**
 - Total sales +12%, or 37.5 MSEK
 - Non-durable goods +16%* or 33.5 MSEK
- **2nd consecutive quarter with warm non-durable sales above 11 MSEK**

Warm Perfusion portion of sales:

- Total 42% (40%)
 - Non-durable goods 36% (31%)
- **New EU sales team up and running**
Strong warm perfusion growth +54% (non-durable goods) outside Americas
(and +21% for Americas).

* Local currency growth +11% for non-durable goods.

Net sales

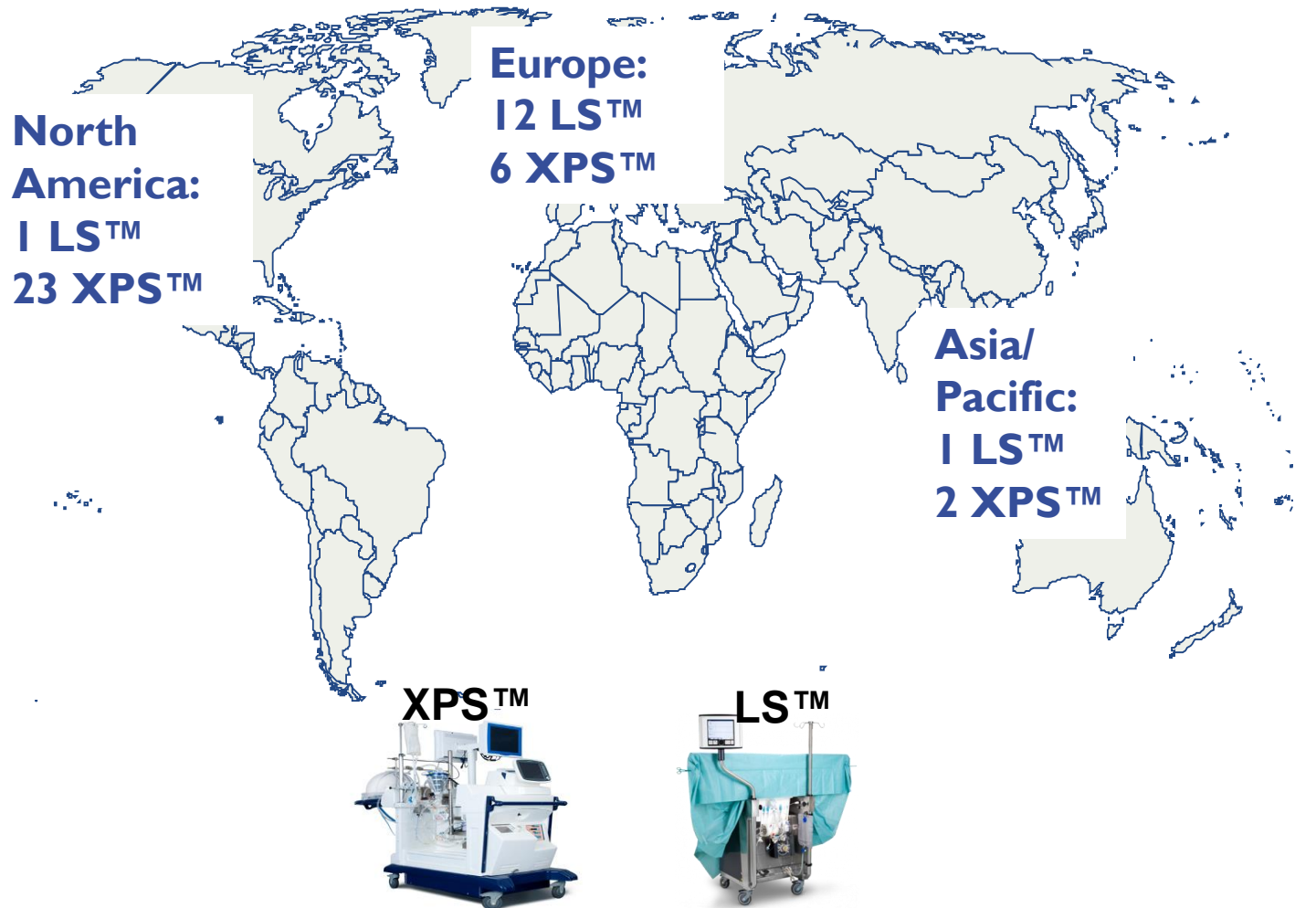


PROFIT & LOSS

		Jan – Mar		Jan – Dec
	(SEK millions)	2017	2016	2016
Sales +12%	Net sales	37.5	33.5	138.2
	Net sales non-Durable goods	33.5	29.1	122.5
Gross profit +12%	Gross profit	27.1	24.3	102.2
	Gross Margin %	72%	72%	74%
	Gross Margin non-Durable goods %	80%	80%	80%
Customer support build up in Q1	Selling expenses excl. items eff. comp%	-30%	-22%	-24%
Nasdaq listing → slightly higher admin cost in 2017	Admin. expenses excl. items eff. comp%*	-12%	-12%	-12%
	R&D exp. excl. Amort. & items eff. comp%*	-17%	-16%	-19%
	Items effecting comparability*	-4%	-7%	-8%
R&D investment new indications	R&D Amortization %*	-7%	-8%	-7%
	Other income/expenses %	-2%	-2%	-2%
	Operating Result %	0%	5%	2%
	EBITDA excl. items eff. comp.*	5.0	7.3	26.4
	EBITDA excl. items eff. comp%	13%	22%	19%
	EBITDA	3.7	4.9	16.0
	EBITDA %	10%	15%	12%

* Items effecting comparability: 2017-Q1 1.4 (2.4) MSEK. R&D Amortization : 2017-Q1 2.6 (2.6) MSEK.

EVLP-machine footprint - 45 XPS™ and LS™



PRODUCTS & MARKETS FOR FUTURE GROWTH

XVIVO - FUTURE GROWTH OPPORTUNITIES



Expansion of Lung transplantation indication, EVLP improvement projects



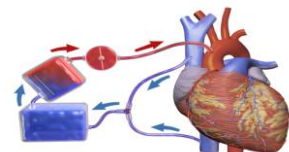
Heart Transplant project in late pre-clinical phase (est. clinical phase in Q2 2017)



STEEN Solution™ for Liver Transplant, early clinical phase



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



PrimECC improve clinical proof, late 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.

Transplantation is a good therapy for deadly diseases but access to usable organs limits its use

	Lung Trans-plantation	Heart Trans-plantation	Liver Trans-plantation
Yearly deaths in organ related diseases	~3 millions	>7 millions	>1 million
No. of transplants / year	~5 000	~6 500	~26 000
5 year survival post Tx	~50%	~70%	~70%
Wait list removal/mortality (USA)	~25%	~25%	~25%
Organ use rate from dead donors (DBD)	~20%	~25%	~80%
DCD share of total Tx (USA)	~2%	-	~6%
Max non-oxygenated time ex-vivo	8 - 12 h	4 - 6 h	8 - 12 h
Perfusion permits use of more organs	DCD & marginal	↑ ex-vivo time	DCD livers
No. of clinics (EU + USA)	~130	~230	~240

DBD = Donation after Brain Death

DCD = Donation after Circulatory (or Cardiac) Death

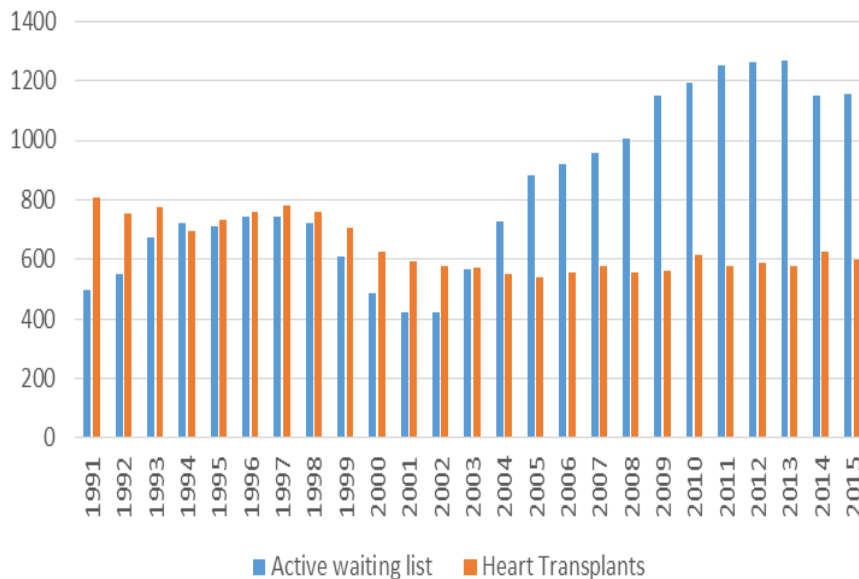
Source: GODT, WHO, UNOS/OPTN, Eurostat, HRSA, Company reports

HEART TRANSPLANT MARKET

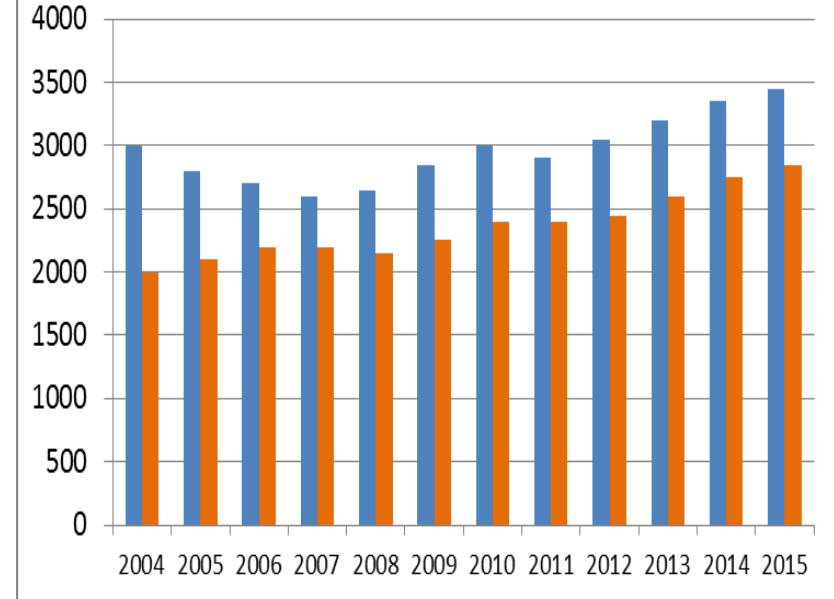


The problem facing heart transplantation is similar to lung transplantation i.e. high waiting list mortality due to lack of organs

Heart waiting list and transplants*



Heart Tx wait list in the USA*



*Eurotransplant - Austria, Belgium, Croatia, Germany, Hungary, Netherlands, Slovenia, Luxembourg

*OPTN/SRTR 2015 Annual Data Report

XVIVO - HEART TRANSPLANTATION

Prof. Steen's research on pigs shows that a heart can be outside the body for 24 hours.



Pre-clinical proof of concept study:

- **Longer preservation time possible with new heart machine and solution:**
 - **Result: transplantation of porcine hearts preserved for 24 hours can be done safely. These preserved hearts had a myocardium that in tests performed as well as hearts not preserved.**
 - **vs. control group: porcine hearts preserved with standard solution for 24 hours - all died within 1 hour.**

Source: <http://dx.doi.org/10.3109/14017431.2016.1154598>



Scandinavian Cardiovascular Journal

ISSN: 1401-7431 (Print) 1651-2006 (Online) Journal homepage: <http://www.tandfonline.com/loi/icdv20>



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

Stig Steen, Audrius Paskevicius, Qiuming Liao & Trygve Sjöberg

To cite this article: Stig Steen, Audrius Paskevicius, Qiuming Liao & Trygve Sjöberg (2016) Safe orthotopic transplantation of hearts harvested 24 hours after brain death and preserved for 24 hours, Scandinavian Cardiovascular Journal, 50:3, 193-200, DOI: [10.3109/14017431.2016.1154598](https://doi.org/10.3109/14017431.2016.1154598)

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XVIVO - HEART TRANSPLANTATION

Heart perfusion and preservation solution and device developed by Prof. Steen

- Pre-clinical proof of concept studies indicate:
 - No non-oxygenated time -> Better organ quality
 - Longer preservation time possible (24h in pigs)
-



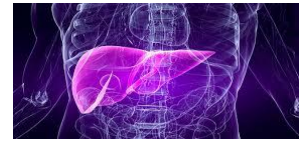
- Next development stages:
 - Proof of concept study to be started Q2 2017
 - After that regulatory study in EU & US
-

- Heart Tx very good fit with XVIVO
 - XVIVO experienced in similar develop. project
 - Synergies in development, regulatory and M&S
 - Same clinics make Heart and Lung Tx

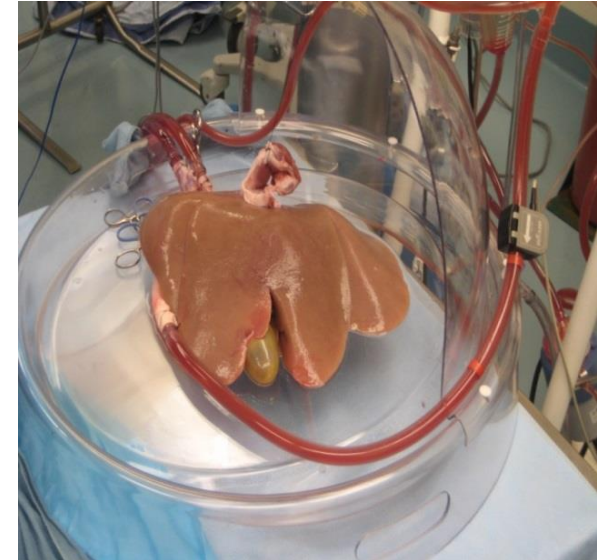


LIVER TRANSPLANTATION

STEEN Solution for evaluation of livers before transplantation



- Liver transplantation market has high potential:
 - Waiting list mortality high ~25%
 - Liver transplant indication x5 compared to lungs
- Marginal DCD livers only way to significantly increase No. of Liver Tx.



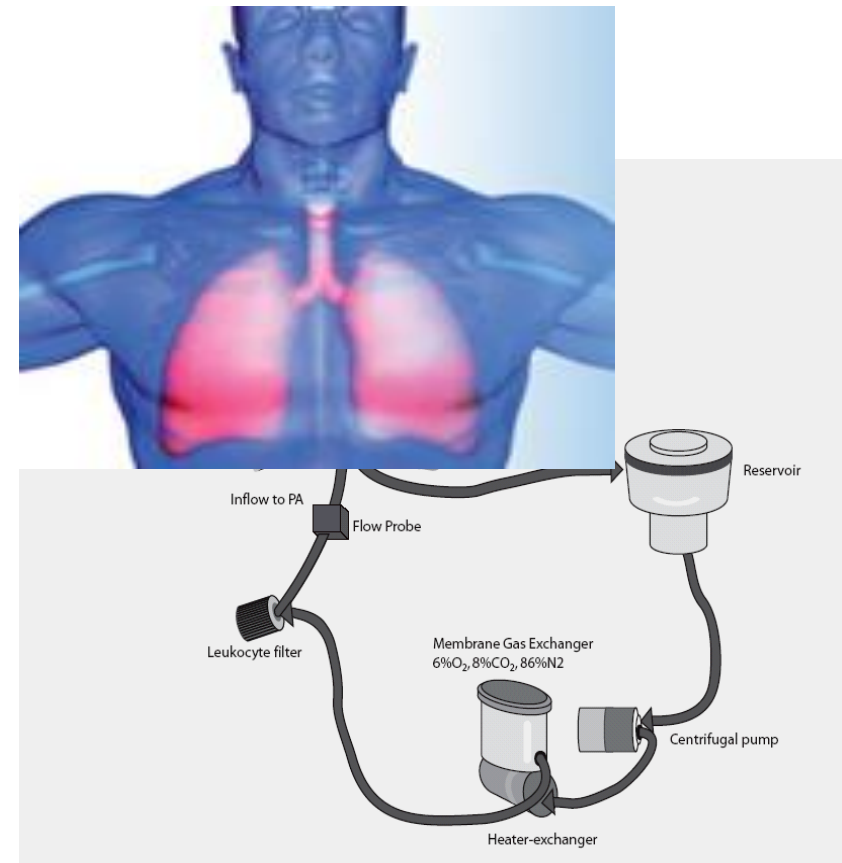
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- Proof of concept study ongoing where DBD livers are perfused with STEEN Solution™ before transplantation
 - First results from clinical study on standard criteria livers published with good clinical results
 - Marginal (DCD) Liver study planned to start in Canada in 2 centers in Q2/Q3 2017

ISOLATED TISSUE THERAPY – CANCER

STEEN Solution as carrier of drugs to optimize treatment

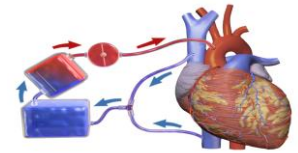


- Problem today with many therapies:
 - Severe side effects on non-targeted organs.
 - Lack of good method to administer drugs to isolated organs or tissues.
- STEEN Solution™ has the potential to be used as a drug delivery carrier for isolated tissues.
- Proof of concept study perfusing lungs in vivo for treatment of cancer is ongoing.



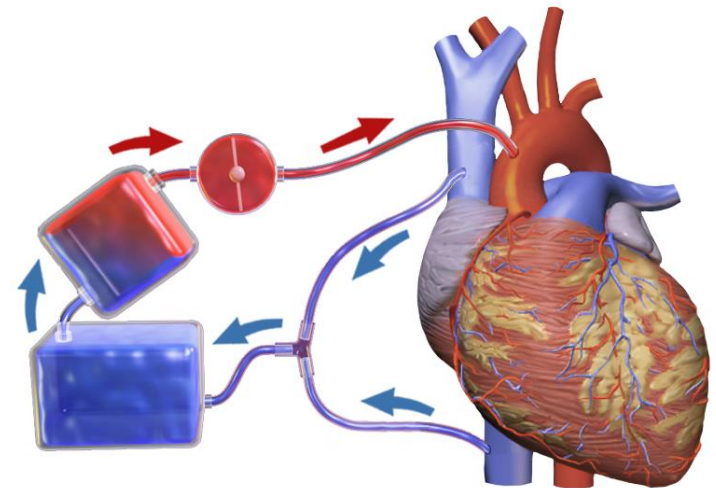
PRIMECC

first tailor made priming solution for heart-lung machines
to avoid side-effects



- **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 per year.
- No FDA approved product for indication
- Previous clinical “proof of concept” study showed interesting results.
- Patent granted in EU, USA and China.
- CE marked Class III Medical Device.

Schematic drawing of heart with heart-lung machine



- Clinical study on 80 patients started in Q2, 2016. Results estimated Q4, 2017

XVIVO PERFUSION

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