

AGM 2017 – CEO MAGNUS NILSSON

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

April 26, 2017

SUMMARY OF XVIVO PERFUSION

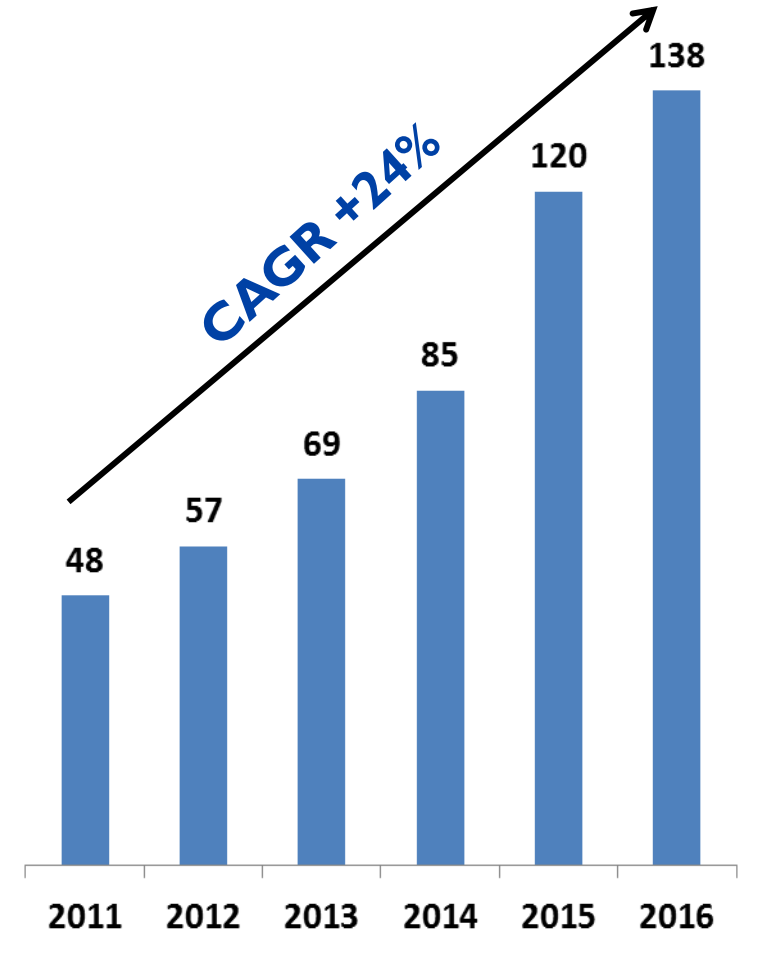
High market demand –
Currently only 10% of need met*

XVIVO has an Unique Patented, Approved
and Documented technology for making
more organs available

XVIVO market leader in Lung Tx
& only with FDA approval for warm
perfusion of Lungs ex-vivo

Strong R&D pipeline for future growth
Several product dev. project in late phase

Sales in MSEK



* GODT 2014 report - <http://www.transplant-observatory.org/data-reports-2014/>

A GLOBAL FOOTPRINT & MANAGEMENT TEAM

Denver, USA - XVIVO Perfusion Inc.

HQ in Gothenburg, Sweden -XVIVO Perfusion AB



CFO



M&S Am.



Development



CEO



M&S
EMEA.



RA / QA

Production and R&D facility in Lund, Sweden
- XVIVO Perfusion Lund

Global sales to all countries where
lung transplants are performed

- Direct sales to ~35 countries
- Sales force in **Americas & EMEA**

> 30 employees at 3 locations

XVIVO PERFORMANCE:

MILE STONES SINCE LISTING (Oct 2012)

- 2012** Sales 54 MSEK; 5 XPS in clinical trial
- 2013** Built capacity & organization (M&S, R&D,etc.)
in Gothenburg and Denver
- 2014-2015** Reg.Approval of XPS-STEEN Solution: EU,
US,Aus. FDA expert panel voted 10-0
- 2015** Sales >100 MSEK; 22 clinics w/ XPS
- 2015-2016** Investment in future growth
Acquired Heart Tx product dev project; Lund
research & prod. facility; Prof Steen collab.
- 2016** Sales 138 MSEK 44 clinics w/ XPS/LS
- Lung Transplant business cash-flow positive

XVIVO technology featured
in media



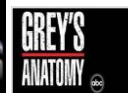
TEDMED2011

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SCIENTIFIC
AMERICAN

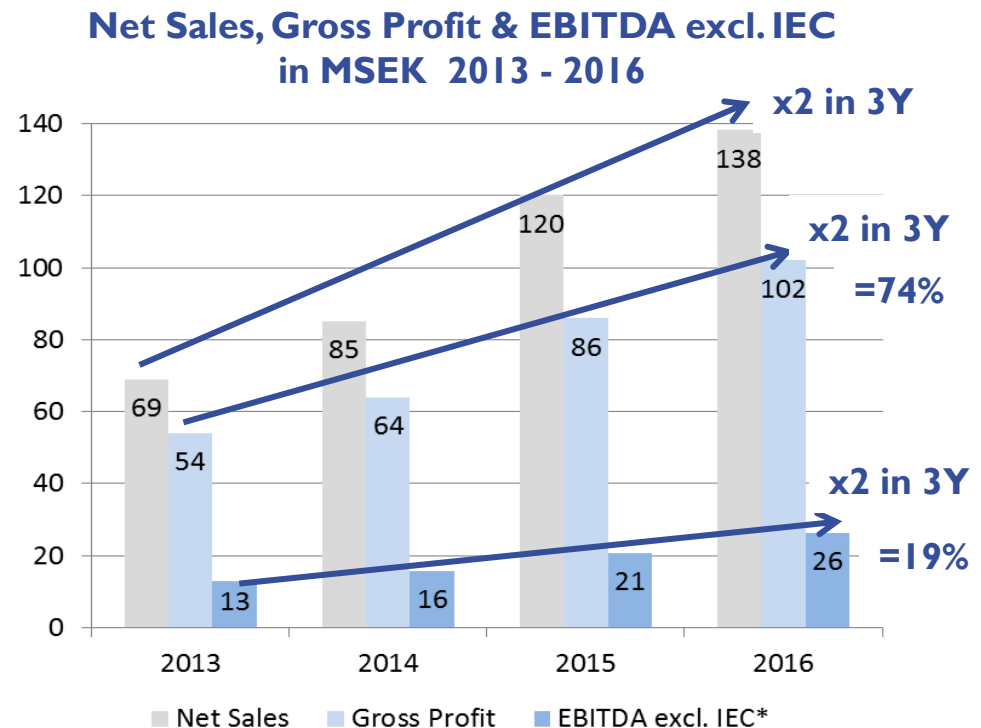
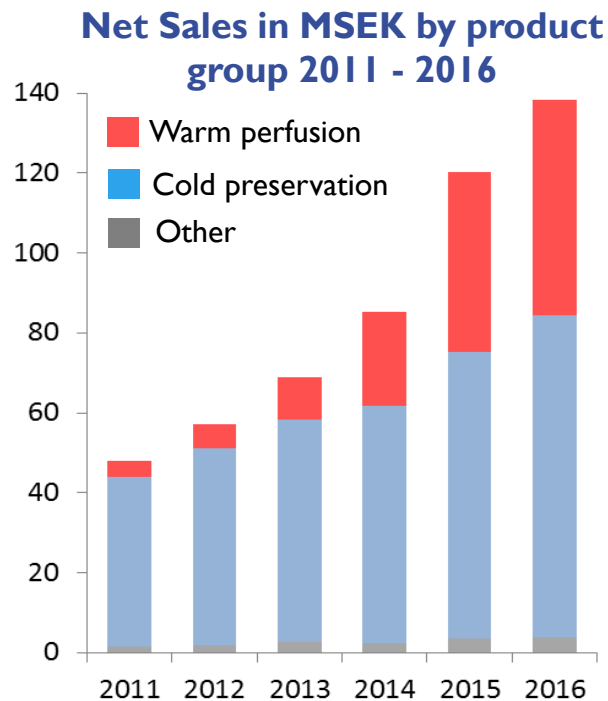
THE GLOBE AND MAIL

THE WALL STREET JOURNAL.



XVIVO PERFORMANCE:

- Sales growth from warm perfusion products, 2011 – 2016 CAGR of +69%
- EBITDA (excl. IEC*) grew during high investments in development and M&S

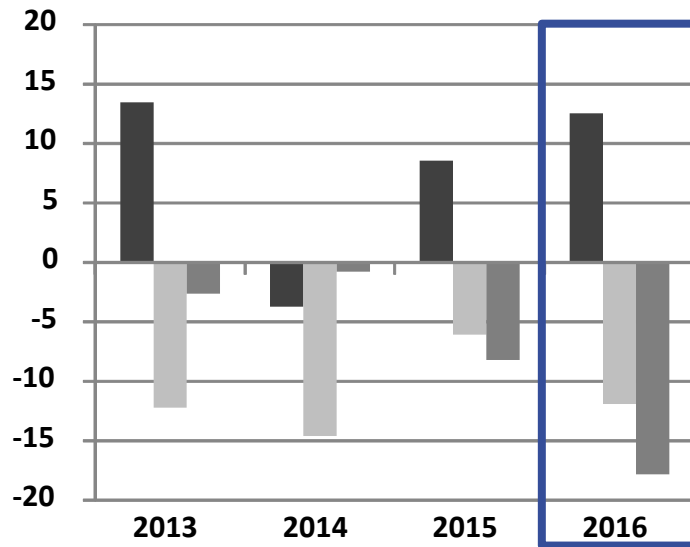


* EBITDA excl. IEC = EBITDA excl. Items effecting Comparability

XVIVO PERFORMANCE:

2016 LUNG BUSINESS CASH-FLOW POSITIVE

Cash-flow MSEK overview
2013 - 2016

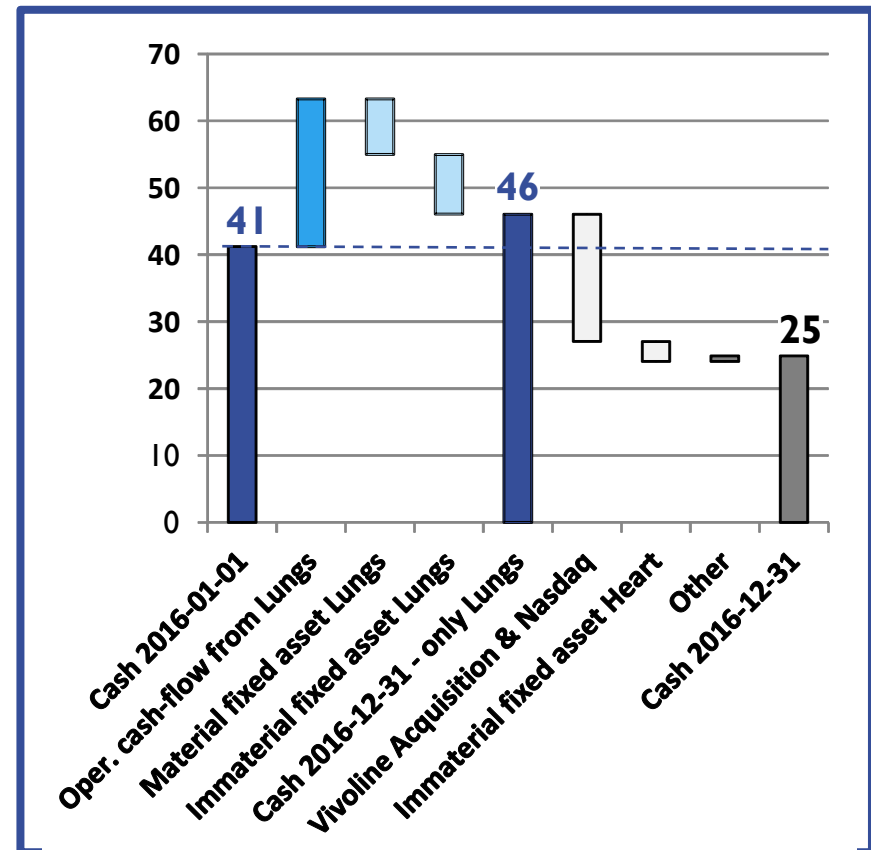


Cash end
of year

4 48 41 25

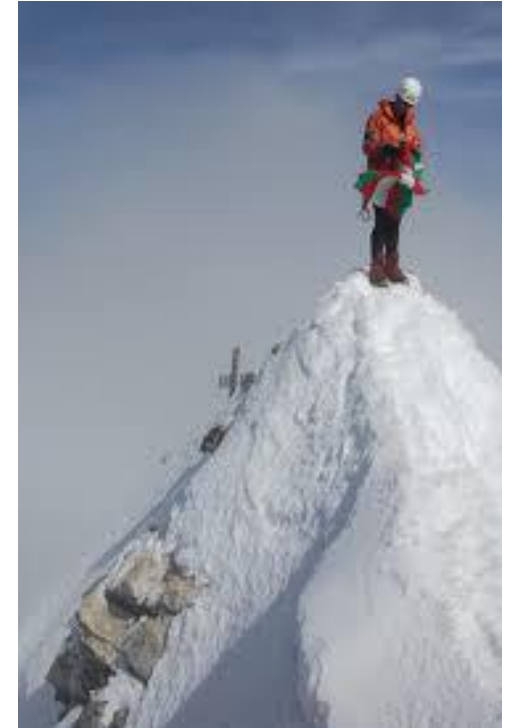
- Operating cash-flow
- Investment into immaterial assets
- Investment into mtrl & financial assets

2016 Cash-flow walk in MSEK divided in
Lung cash-flow and Other cash-flow



RESULTS OF VIVOLINE ACQUISITION (Q2 2016)

- **Larger footprint on lung transplant market**
- **Position to be global leader in Thorax transplantation (Heart & Lungs)**
- **Stronger R&D pipeline and increased R&D capacity**
- **Renewed collaboration with Prof. Steen's and his research institute**
- **Cleanroom production facility**



Integration of Vivoline into XVIVO M&S, R&D and Admin. completed in 100 days

2016

HIGHLIGHTS 2016

- Sales 138 MSEK with growth +15%
 - 10 XPS™/LS™ delivered
- EBITDA excl. IEC* 26 MSEK (21) = 19% (17%)
- Integration of Vivoline complete –
LS™ & DLS™ now sold by XVIVO's M&S team
- Nasdaq Stockholm listing (mid cap)
- Strengthen R&D portfolio:
 - Heart transplant project acquired
 - Liver transplant clinical study – good initial results
 - Clinical STEEN Solution cancer study started
 - PrimECC clinical study started (CE-marked & patented)

*EBITDA excl. IEC = EBITDA excluding items effecting comparability



PROFIT & LOSS 2016

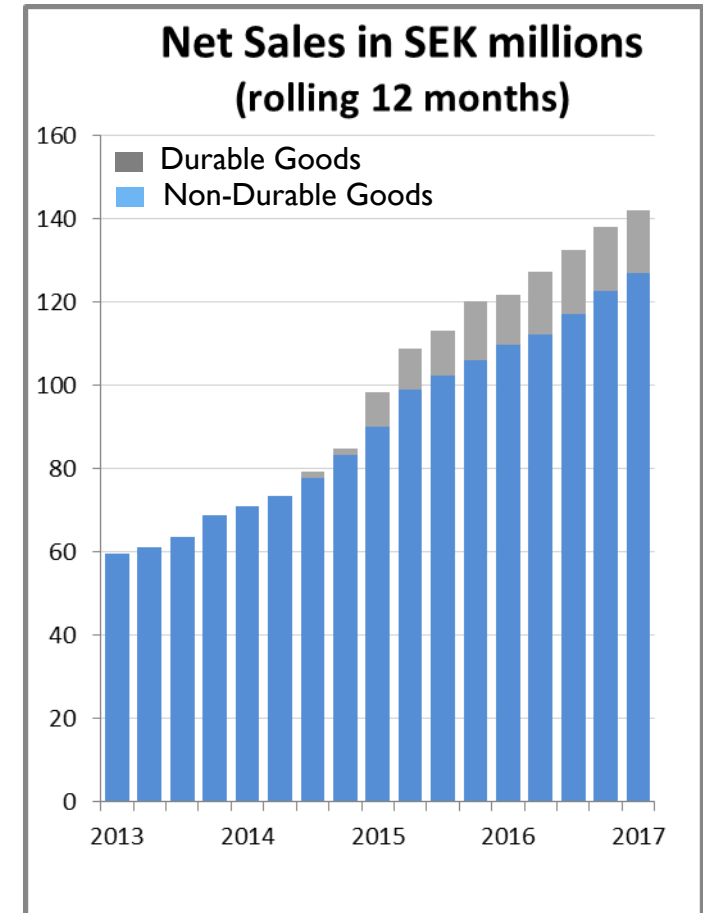
		Jan – Dec	Jan – Dec
	(SEK millions)	2016	2015
Sales +15%	Net sales	138.2	120.2
	Net sales non-Durable goods	122.5	106.0
Gross profit +20%	Gross profit	102.2	85.0
	Gross Margin %	74%	71%
	Gross Margin non-Durable goods %	80%	78%
R&D investment new indications	Selling expenses excl. items eff. comp%	-24%	-27%
	Admin. expenses excl. items eff. comp%*	-12%	-10%
Vivoline / Nasdaq	R&D exp. excl. Amort. & items eff. comp%*	-19%	-16%
	Items effecting comparability*	-8%	-2%
	R&D Amortization %*	-7%	-8%
	Other income/expenses %	-2%	-1%
	Operating Result %	2%	6%
EBITDA +27%	EBITDA excl. items eff. comp.*	26.4	20.8
excl. items effecting comp.	EBITDA excl. items eff. comp%	19%	17%
	EBITDA	16.0	18.8
	EBITDA %	12%	16%

2017 Q1

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

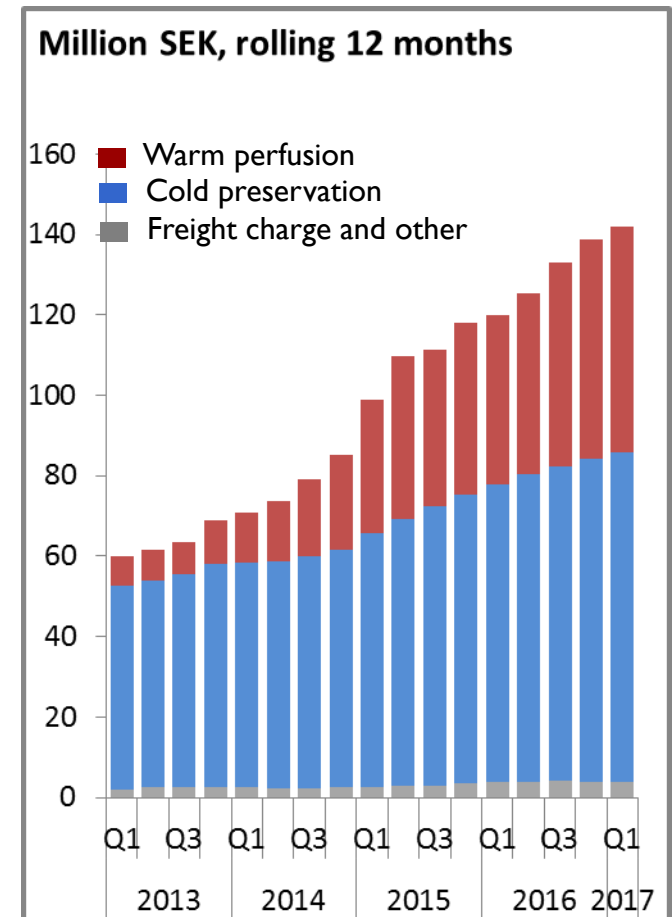
- **Sales:**
 - Total sales +12%, or 37.5 MSEK
 - Non-durable goods +16%* or 33.5 MSEK
- **2nd consecutive quarter with warm non-durable sales above 11 MSEK**

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



PRODUCTS & MARKETS FOR FUTURE GROWTH

XVIVO - FUTURE GROWTH OPPORTUNITIES



Expansion of Lung transplantation indication, EVLP improvement projects



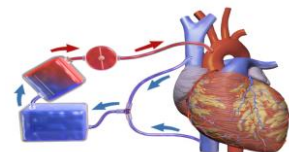
Heart Transplant project in late pre-clinical phase (est. clinical phase in Q2 2017)



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

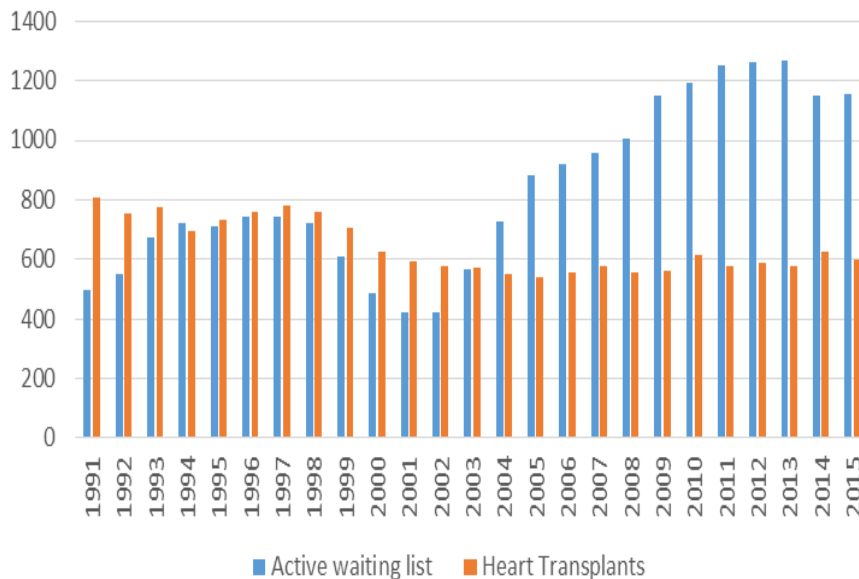
Source: GODT, WHO, UNOS/OPTN, Eurostat, HRSA, Company reports

HEART TRANSPLANT MARKET

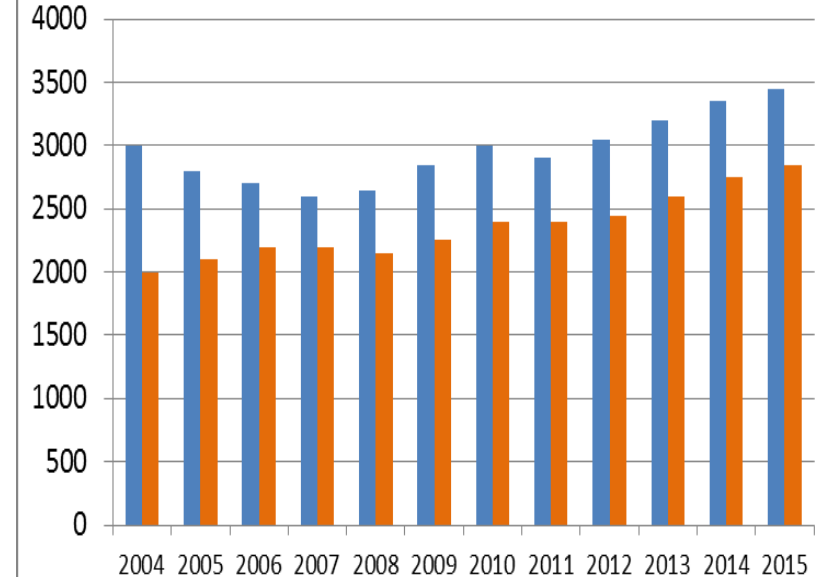


The problem facing heart transplantation is similar to lung transplantation i.e. high waiting list mortality due to lack of organs

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)

To link to this article: <http://dx.doi.org/10.3109/14017431.2016.1154598>



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Accepted author version posted online: 16 Feb 2016.
Published online: 04 Apr 2016.



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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)
-

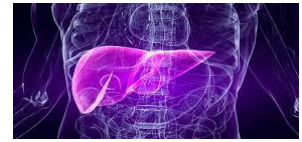
- Next development stages:
 - Proof of concept study to be started Q2 2017
 - After that regulatory study in EU & US
-

- 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

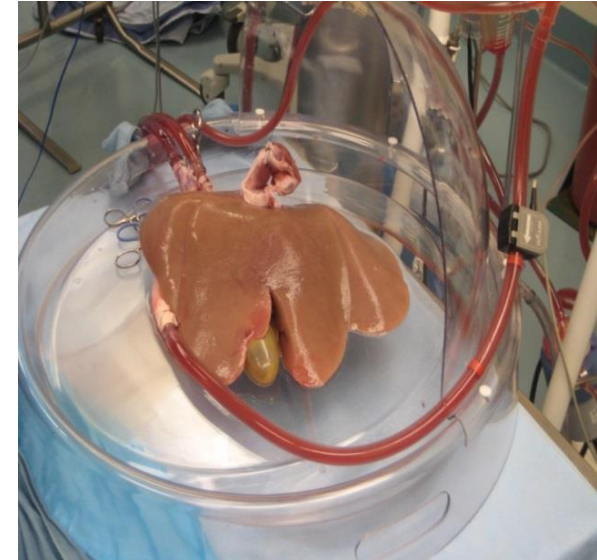


LIVER TRANSPLANTATION

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.**



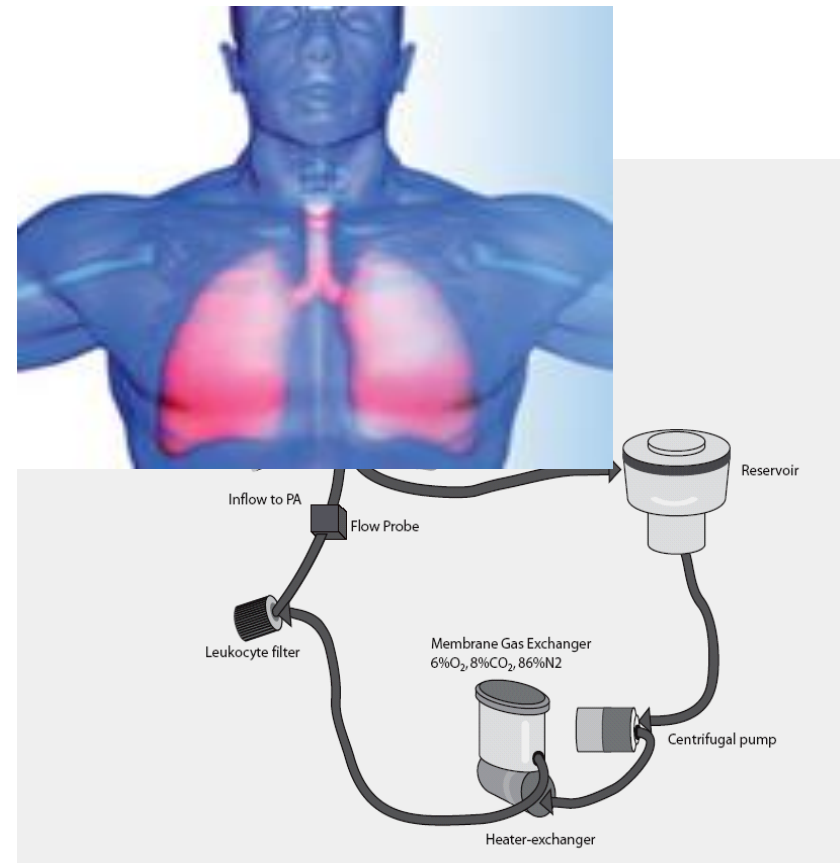
-
- **Proof of concept study ongoing where DBD livers are perfused with STEEN Solution™ before transplantation**
 - **First results from clinical study on standard criteria livers published with good clinical results**
 - **Marginal (DCD) Liver study planned to start in Canada in 2 centers in Q2/Q3 2017**

ISOLATED TISSUE THERAPY – CANCER

STEEN Solution as carrier of drugs to optimize treatment

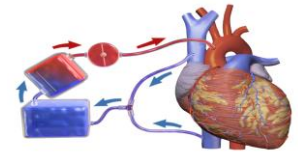


- Problem today with many therapies:
 - Severe side effects on non-targeted organs.
 - Lack of good method to administer drugs to isolated organs or tissues.
- STEEN Solution™ has the potential to be used as a drug delivery carrier for isolated tissues.
- Proof of concept study perfusing lungs in vivo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



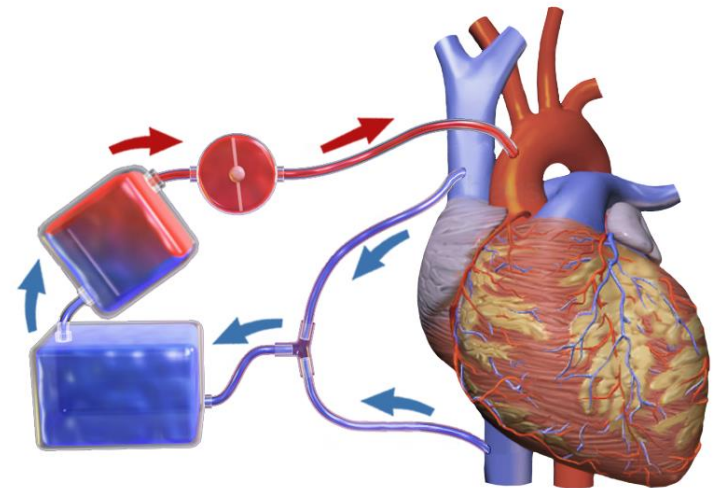
PRIMECC

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