

# AGM 2018 – CEO MAGNUS NILSSON

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

April 27, 2018

20 YEARS  
of NEW HORIZONS IN  
TRANSPLANTATION

XVIVO  
PERFUSION

# SUMMARY OF XVIVO PERFUSION

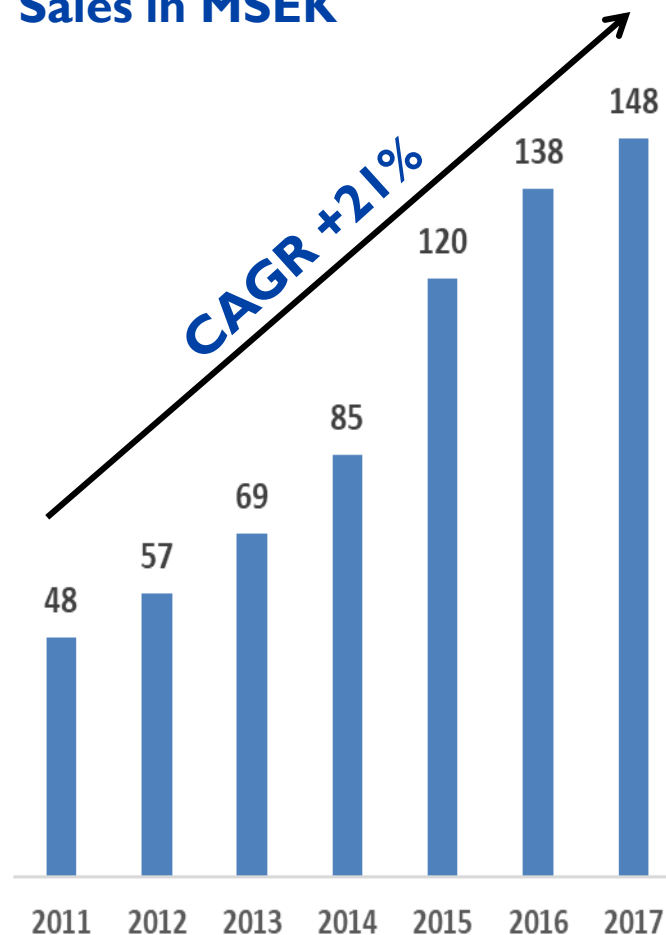
High market demand –  
Currently only 10% of need met\*

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

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

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

Sales in MSEK



\* Data from GODT

# A GLOBAL FOOTPRINT & MANAGEMENT TEAM

**Denver, USA - XVIVO Perfusion Inc.**



**CEO Development**

**HQ in Gothenburg, Sweden - XVIVO Perfusion AB**



**CFO M&S RA / QA  
EMEA.**

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

**Global sales to all countries where lung  
transplants are performed**

- **Direct sales to ~40 countries**
- **Sales force in Americas & EMEA**
- **36 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,  
Aus. & USA → 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**      **Lung Transplant business cash-flow positive**
  
- 2017**      **Sales 148 MSEK - 46 clinics w/ XPS/LS**

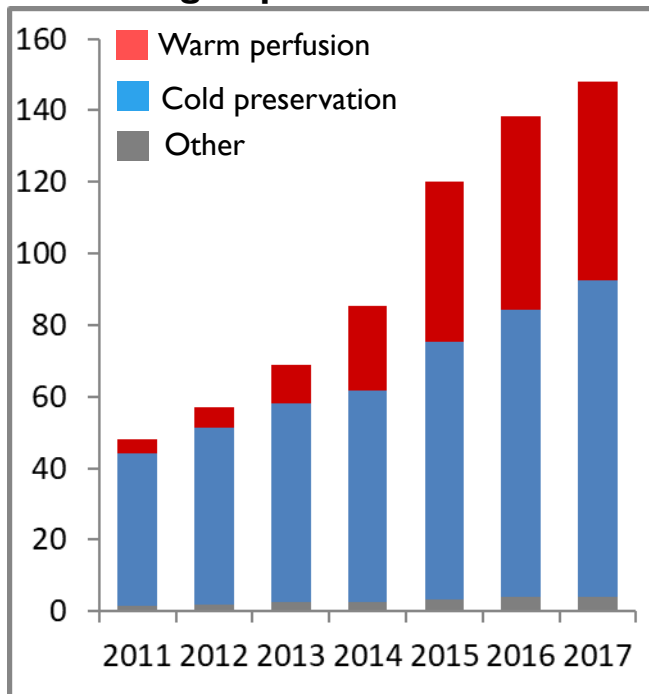
**XVIVO technology featured  
in media**



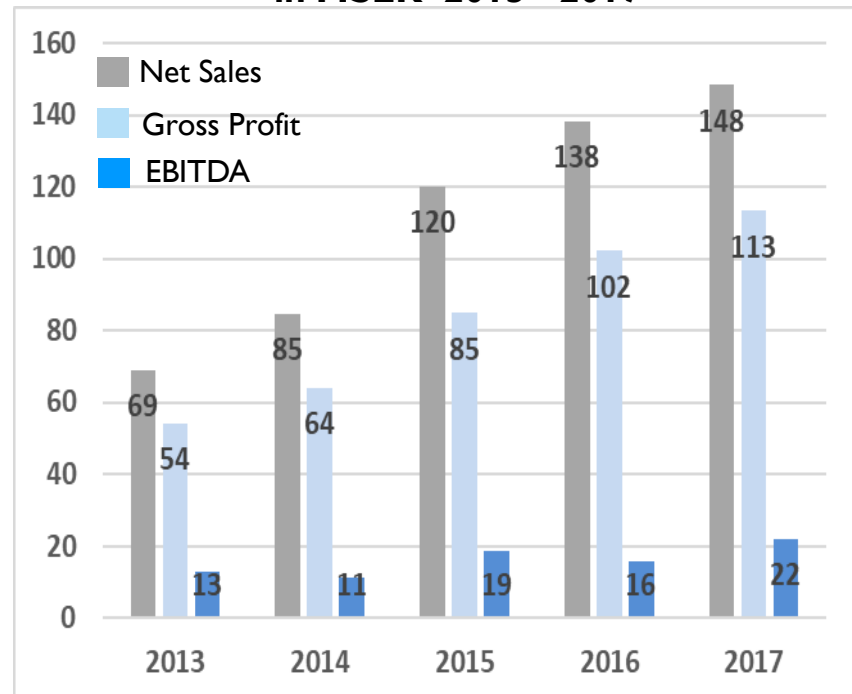
# XVIVO PERFORMANCE:

- Sales growth from warm perfusion products, 2011 – 2017 CAGR of +55%
- EBITDA grew during high investments in development and M&S
- Profitable growth every quarter since 2003

Net Sales in MSEK by product group 2011 - 2017



Net Sales, Gross Profit & EBITDA in MSEK 2013 - 2017





20 YEARS OF INNOVATION



1998



*Company founded by Dr. Magnus Nilsson.  
Research collaboration with Prof. Stig Steen and  
University Hospital in Lund.*

1999

*Research collaboration with Prof. Shaf  
Keshavjee and University Hospital Toronto.*

2000

*First clinical EVLP lung transplant with STEEN  
Solution™ performed in Lund by Prof. Stig  
Steen. Published in Lancet (2001).*

2001



*PERFADEx® FDA clearance.*



2006



*STEEN Solution™ CE marked.*

2008

*First STEEN Solution™ clinical study (HELP) initiated in Toronto with Prof. Shaf Keshavjee . Positive results published in New England Journal of Medicine (2011).*



2011

*Clinical NOVEL study initiated in several leading transplantation clinics in US.*

2014



*The first warm perfusion device, XPS™ and STEEN Solution™, approved by the FDA under HDE.*

*XPS™ CE marked.*

2016

*Acquisition of Vivoline. With LS, enabling Scandinavian EVLP protocol.*

*PrimECC® CE marked.*

2017



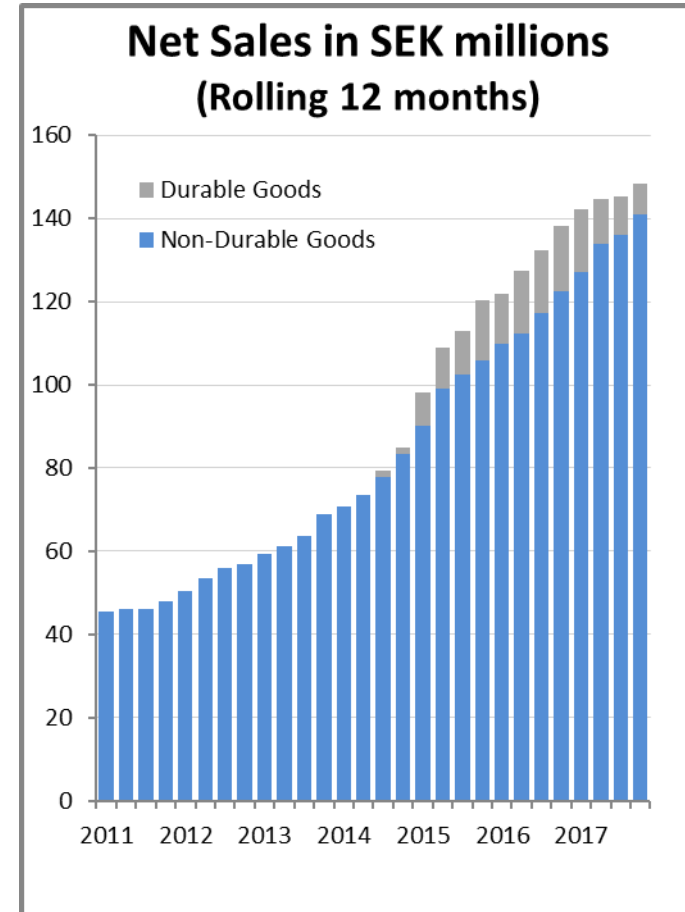
*First clinical heart transplant using heart preservation technique developed by XVIVO's partner Prof. Stig Steen was performed at University Hospital in Lund by Prof. Johan Nilsson.*

*Clinical trial on PrimECC® at Sahlgrenska University Hospital completed.*

2017

# HIGHLIGHTS 2017

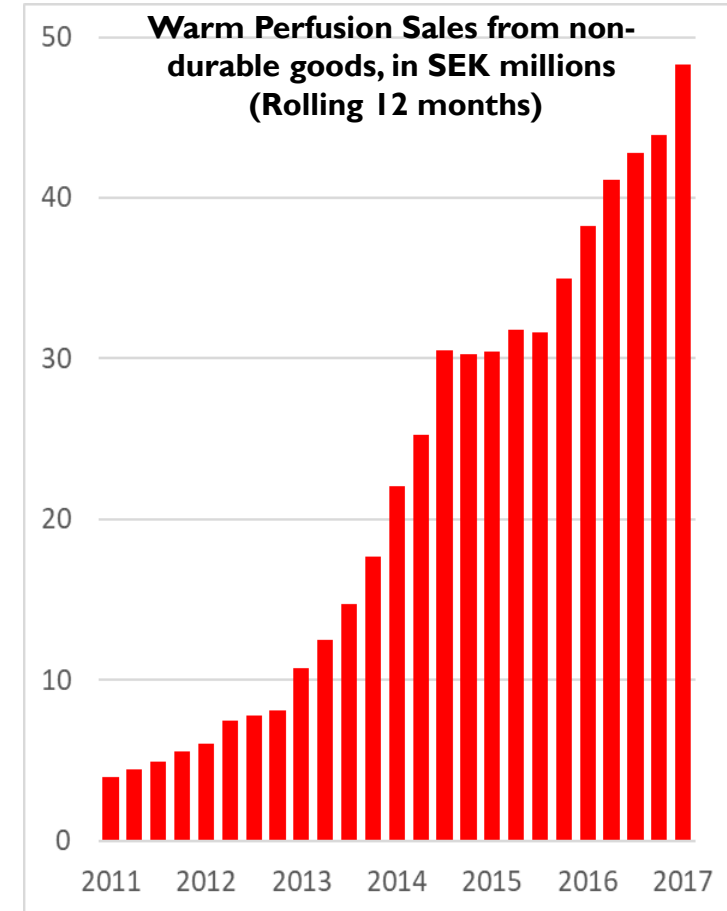
- **The first clinical heart transplant using the heart preservation technology developed by XVIVO's partner Professor Stig Steen was performed.**
- **All 220 patients included in the NOVEL study in the US which will form the basis of the company's PMA application.**
- **PrimECC study on 80 patients at Sahlgrenska University Hospital completed.**
- **A private placement of SEK 181 million was carried out to accelerate XVIVO's heart transplant project to the market.**



# SALES HIGHLIGHTS 2017

## DOUBLE DIGIT GROWTH FOR NON-DURABLE SALES

- **Sales:**
  - Non-durable goods increased by 15%\* to 141 MSEK.
  - Net sales increased by 7% to 148 MSEK.
- **4 new countries with XPS™ or LS™**
  - Australia
  - China
  - Portugal
  - the Netherlands
- **EVLP reimbursement codes (CPT) obtained in the US.**



\* Local currency growth +15% for non-durable goods.

# PROFIT & LOSS

*Sales non-durable  
+15%*

*Customer support  
build up*

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

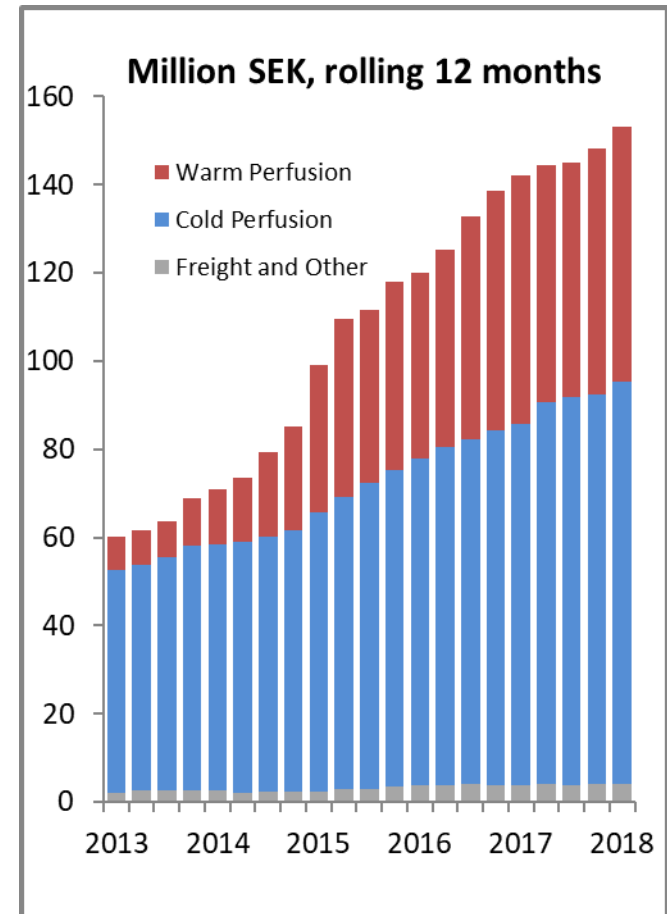
(SEK Millions)	2017	2016
<b>Net sales</b>	<b>148.3</b>	<b>138.2</b>
<b>Net sales non-Durable goods</b>	<b>141.0</b>	<b>122.5</b>
<b>Gross profit</b>	<b>113.4</b>	<b>102.2</b>
<b>Gross Margin %</b>	<b>76%</b>	<b>74%</b>
<b>Gross Margin non-Durable goods %</b>	<b>78%</b>	<b>80%</b>
<b>Selling expenses excl. items eff. comp%</b>	<b>-29%</b>	<b>-24%</b>
Admin. expenses excl. items eff. comp%*	-13%	-12%
R&D exp. excl. Amort. & items eff. comp%*	-18%	-19%
Items effecting comparability*	-2%	-8%
R&D Amortization %*	-7%	-7%
Other income/expenses %	-2%	-2%
Operating Result %	5%	2%
<b>EBITDA excl. items eff. comp.*</b>	<b>24.8</b>	<b>26.4</b>
<b>EBITDA excl. items eff. comp%</b>	<b>17%</b>	<b>19%</b>
<b>EBITDA</b>	<b>22.0</b>	<b>16.0</b>
<b>EBITDA %</b>	<b>15%</b>	<b>12%</b>

\* Items effecting comparability: 2017 2.8 (10.4) MSEK. R&D Amortization : 2017 10.6 (10.3) MSEK.

2018 – Q1

# HIGHLIGHTS 2018 – Q1

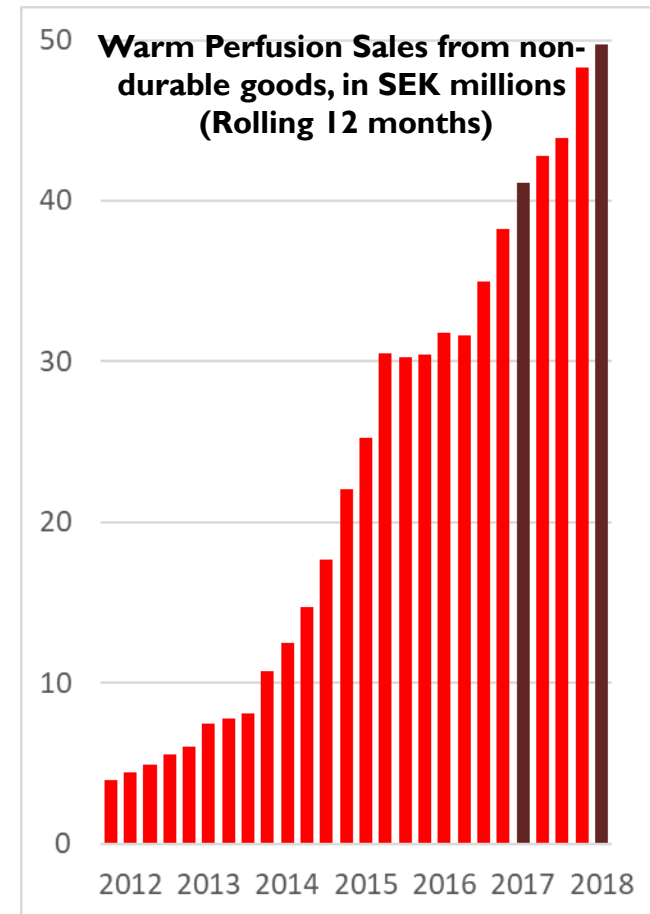
- **Net sales exceeded SEK 150 million per rolling 12 months for the first time.**
- **Cash flow from operating activities was SEK 9.2 (-2.0) million. Intangible investments SEK 8.7 (6.0) million.**
- **2 XPS™ were delivered during the quarter.**
- **XVIVO's prototype of a heart transplantation machine has been completed for technical testing.**





# SALES HIGHLIGHTS 2018 – Q1

- **Net Sales grew +18% in local currencies to 42.5 MSEK.**
- **Net Sales non-durable goods increased by +17% in local currencies to 37.9 MSEK.**
- **Second strongest quarter in Warm perfusion, after a strong Q4 2017.**
- **Rolling 12 months Warm perfusion growth of +21% (YoY).**



# PROFIT & LOSS

	2018 Jan- Mar	2017 Jan- Mar	2017 Whole year
(SEK Millions)			
Net sales	42.5	37.5	148.3
Net sales non-Durable goods	37.9	33.6	141.0
Gross profit	30.1	27.1	113.4
Gross Margin %	71%	72%	76%
Gross Margin non-Durable goods %	77%	80%	78%
Selling expenses excl. items eff. comp%	-24%	-30%	-29%
Admin. expenses excl. items eff. comp%*	-11%	-13%	-13%
R&D exp. excl. Amort. & items eff. comp%*	-21%	-19%	-18%
Items effecting comparability*	0%	-4%	-2%
R&D Amortization %*	-6%	-7%	-7%
Other income/expenses %	-1%	-2%	-2%
Operating Result %	7%	0%	5%
EBITDA excl. items eff. comp.*	7.2	5,0	24.8
EBITDA excl. items eff. comp%	17%	13%	17%
EBITDA	7.2	3.7	22.0
EBITDA %	17%	10%	15%

**Sales non-durable  
+17% local currencies**

**Customer support  
build up, cost lower  
due to vacancies filled  
in end of Q1**

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

Items effecting comparability: 2018 0 (1.4) MSEK. R&D Amortization : 2018 2.7 (2.6) MSEK.

# ISHLT CONGRESS

## International Society of Heart and Lung Transplantation

- The upgraded **XPS™** drew much attention and appreciation.
- Results were presented from the first transplantation using the new heart preservation technology developed by Professor Steen.
- Clinics from all over the world showed great interest.



# XPS UPGRADE PROGRAM

- **Improved usability – e.g. Barcode scanner**
  - Functions added to simplify the EVLP process and improve ease of use for the surgical team.
- **Improved output – e.g. Online scale for continuous measuring of the weight of the lung**
  - More parameters to ensure that the surgical team can take more informed decisions.



# PRODUCTS & MARKETS FOR FUTURE GROWTH

# TRANSPLANT MARKET - OVERVIEW

	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
Annual growth (no. of Tx)	+7%	+4%	+4%
No. of clinics (EU + USA)	~130	~230	~240
Organ use rate from dead donors	~20%	~25%	~80%
Wait list removal/mortality (USA)	~25%	~25%	~25%
Max accepted ischemic time	8 - 12 h	4 - 6 h	8 - 12 h
5 year survival post Tx	~50%	~70%	~70%
DCD share of total Tx (USA)	~2%	-	~6%
Possibility of ex vivo evaluation	Yes	-	-
Possibility to step change	DCD & marginal	↑ Ischemic time	DCD livers

Customer overlap high - 62 / 67 Lung Tx clinics in the US performed all three.

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

# MARKET POTENTIAL PER INDICATION

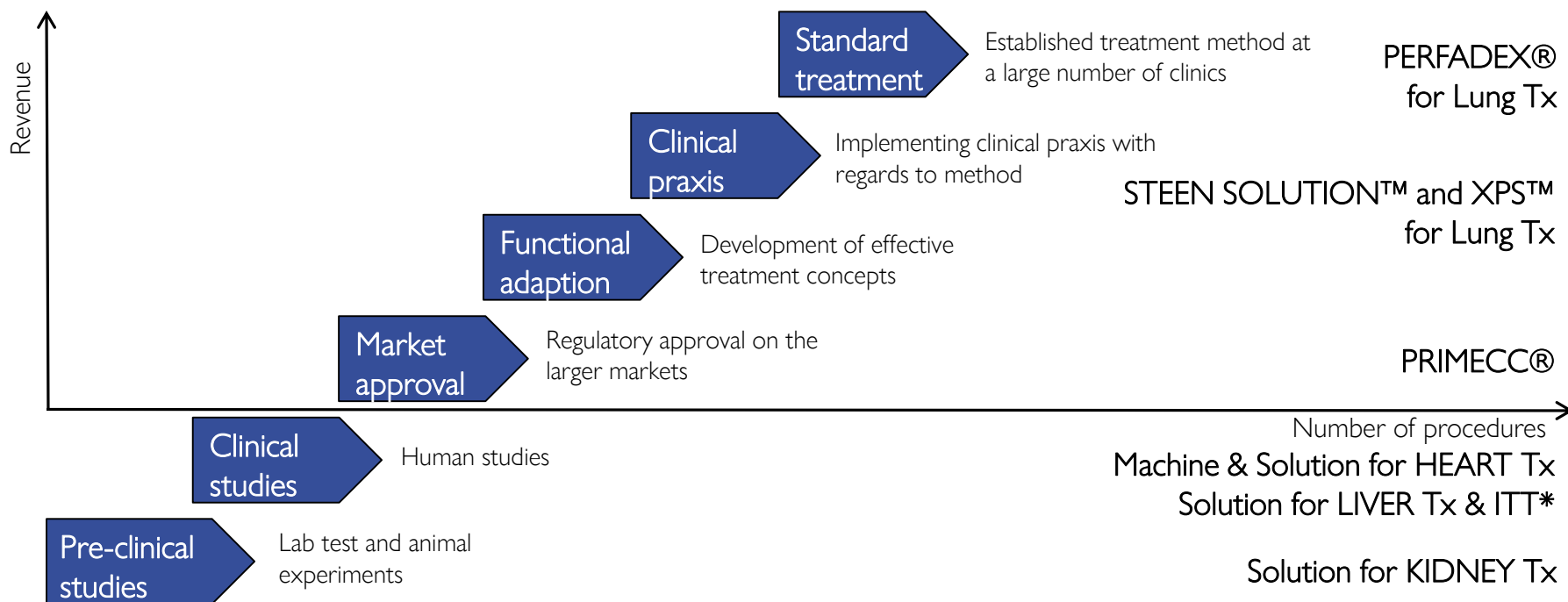
	Potential Lung Transplantation	Potential Heart Transplantation	Potential Liver Transplantation
Product	Perfadex®, STEEN Solution™ and XPS™	Heart Solution and Heart XPS™	STEEN Solution™ and Liver XPS™
Possible usage of organ	40% of DBD* → 20% of DCD*	50% of DBD* → 5% of DCD*	80% of DBD* → 10% of DCD*
Market in no. of organ transplants/ evaluations	~10,000 → ~50,000	~13,000 → ~20,000	~26,000 → ~50,000
Sales per organ transplant	~130,000 SEK	~130,000 SEK	~130,000 SEK
Market potential	~1,000 → ~5,000 MSEK	~2,000 → ~3,000 MSEK	~2,500 → ~5,000 MSEK

\* DBD = Donation after Brain Death

\* DCD = Donation after Circulatory (or Cardiac) Death. Maastricht criteria II-IV considered suitable for donation

Source: Management accounts

# DEVELOPMENT STEPS



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



# XVIVO - FUTURE GROWTH OPPORTUNITIES



**Expansion of Lung transplantation indication, EVLP improvement projects, increase of DCD**



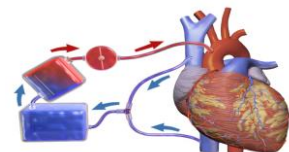
**Heart Transplant project, early clinical phase**



**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.

# LUNG TRANSPLANTATION

XPS & STEEN Solution the only FDA (HDE) approved device for warm perfusion of marginal lungs

## **NOVEL study & Post Approval Study (PAS) :**

- ☒ 110 + 110 patients included
- ☐ Follow-up 1 year – May 2018
- ☒ Study analysis ongoing
- ☐ PMA application submission – May 2018
  
- ☐ PAS (Post Approval Study)
  - ☒ 126 + 126 inclusion completed
  - ☐ Follow-up 3 years
  
- ☒ Restrictions on patients and recipients removed since PAS inclusion finalized



# LUNG TRANSPLANTATION

## Next steps for lung warm perfusion (EVLP)

### **XVIVO will continue to clinically develop EVLP:**

- Use of DCD\* donors for transplantation
  - controlled / uncontrolled
- Ex Vivo Infection therapy through EVLP e.g. Pneumonia therapy and virus reduction
  - 17 Hep C infected lungs transplanted
- Investigate immunological response with EVLP targeting long term survival
- New markers and online parameters for better decision making



\*Donation after Circulatory Death

# XVIVO - HEART TRANSPLANTATION

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

## First clinical HTx with new technology:

- First patient transplanted with the new technology (new solution and new machine)
- Proof of concept study with 6 patients.
- Now approved for air transportation

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

Stig Steen, Audrius Paskevicius, Qiuming Liao & Trygve Sjöberg

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## Pre-clinical proof of concept studies indicate:

- No non-oxygenated time -> Better organ quality
- Longer preservation time possible (24h in pigs)
- Myocardium tests on hearts preserved and not preserved showed similar results.

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## Main focus of next phase in heart transplant area:

- Prototype for international study ready for technical testing.
- Production development of heart perfusion solution.



# PRIMECC – STUDY INCLUSION FINALIZED

## **PRIMECC® developed to avoid side-effects when priming heart-lung machines:**

- Patent granted in EU, USA, China & Japan.
- CE marked Class III Medical Device.
- Inclusion of 40+40 patients completed 2018.
- Analysis of key parameters completed

## **Next steps:**

- Expert review of study results ongoing.
- Follow up studies for key findings - planning ongoing.



# SUMMARY OTHER NEW INDICATIONS

## **Liver transplantation:**

- Results from first clinical study on 20 patients with STEEN Solution shows good clinical results.
- Marginal (DCD) Liver study planned to start in Canada in 2 centers - Preparations ongoing.



## **Isolated Tissue Therapy – Cancer**

- Proof of concept study perfusing lungs in vivo for treatment of cancer is ongoing.
- Second patient successfully treated and followed up.



# OUTLOOK 2018 - FOCUS AREAS

## Thoracic Surgery

- Lungs - Continue to increase footprint and use of EVLP technology
- Lungs - PMA application and submission in May
- Lungs - Reinforced clinical development of EVLP
- Lungs – Hepatis C infected donors study
- Heart - Accelerating Heart transplant project with aim of international clinical study
- PrimECC – Expert review of PrimECC clinical data and start of clinical documentation program (US application + Marketing)

## R&D - New indications

- Liver - STEEN Solution™ clinical development for Liver Tx
- 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 and build a new business in new indications using the STEEN Solution technology.**

# 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**