

33RD QUARTERLY REPORT

REPORT ON OPERATIONS

JAN – DEC 2020

TELEPHONE CONFERENCE

January 28th, 2020

DAG ANDERSSON, CEO

KRISTOFFER NORDSTRÖM, CFO



HIGHLIGHTS Q4

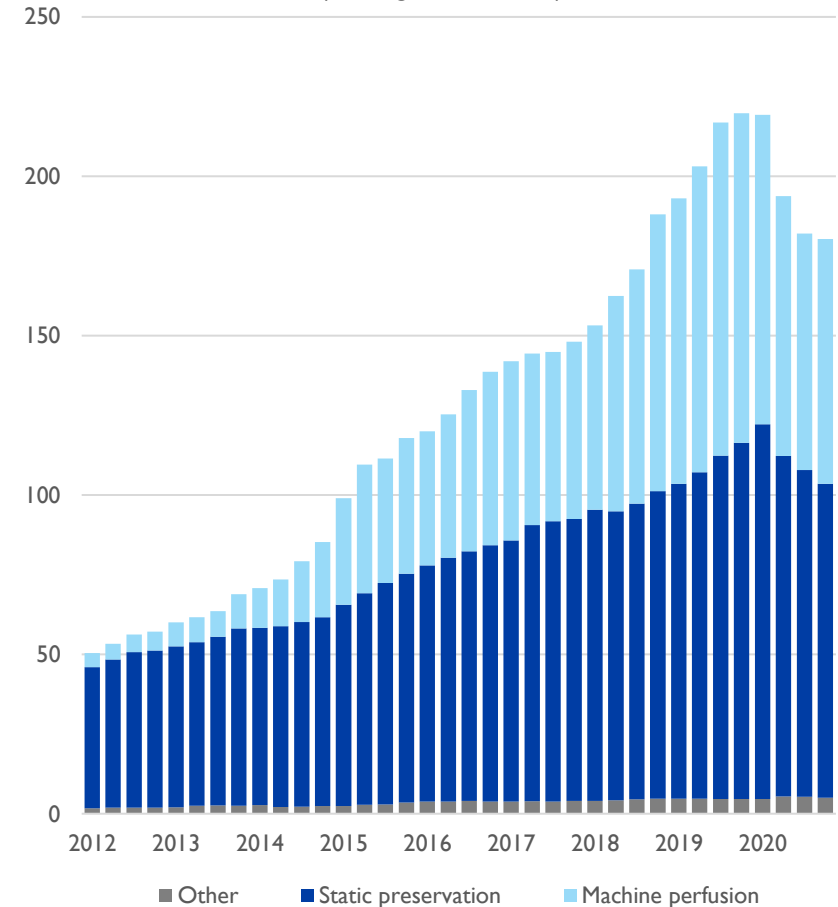
- ▶ **The first patients transplanted in the EU Heart preservation study**
 - ▶ Four centers out of nine are now ready to include patients
- ▶ **The Lancet publication shows positive study results**
 - ▶ Better survival of transplanted kidneys after cold, oxygenated machine perfusion
- ▶ **The new business area, Abdominal, added a 26% acquired growth in Net Sales**
- ▶ **Net Sales (incl. durable goods) +2% in LC¹ (-3% in SEK)**
- ▶ **Non-durable² sales -2% in LC (-8% in SEK)**
- ▶ **Gross margin Non-durable sales of 72% (77%)**
- ▶ **Positive adjusted EBITDA³ of 11% (13%)**

¹ Local currency

² Including sales from solutions, kits, freight and service

³ EBITDA adjusted with costs associated with a share-based bonus program for employees outside Sweden and integration costs, 13,2 MSEK in total.

Net Sales in MSEK
(rolling 12 months)





FINANCIAL INFORMATION

NET SALES & GROSS MARGIN

Q4 MSEK	Non-Durable goods		Durable Goods		Total	
	2020	2019	2020	2019	2020	2019
Total						
Net Sales	54.9	59.4	5.4	3.0	60.3	62.4
Gross margin	72%	77%	29%	3%	69%	73%

Thoracic						
Net Sales	41.1	59.4	2.6	3.0	43.7	62.4
Gross margin	80%	77%	18%	3%	76%	73%

Abdominal						
Net Sales	13.9	-	2.7	-	16.6	-
Gross margin	50%	-	41%	-	48%	-

Full year	Non-Durable goods		Durable Goods		Total	
	2020	2019	2020	2019	2020	2019
Total						
Net Sales	169.4	206.9	10.4	14.0	179.9	220.8
Gross margin	77%	77%	24%	24%	74%	74%

HIGHLIGHTS

- ▶ Net Sales: +2 % in LC
- ▶ Organic growth: -25 % in LC
- ▶ Acquired growth: +26 % in LC

- ▶ Sales of Non-Durable goods: -26 % in LC
- ▶ Machine perfusion portion: 36 % of Sales of non-durable goods
- ▶ Gross margin on Non-Durable goods: 80%

- ▶ Machine perfusion portion: 100 %
- ▶ Local currency growth: 60 % in LC
- ▶ Gross margin on Non-Durable goods: 50 %

- ▶ Net Sales -17 % in LC
- ▶ Sales of Non-Durable goods -16 % in LC

- ▶ Machine perfusion portion: 43 % of Net Sales
- ▶ Organic growth: -24 % in LC. Acquired growth: +7 % in LC
- ▶ Gross margin in line with last year

PROFIT & LOSS

(MSEK)	Oct-Dec		Full year	
	2020	2019	2020	2019
Net Sales	60	62	180	221
Net Sales	55	59	169	207
Non-Durable goods				
Gross profit	41	46	133	163
Gross Margin %	69%	73%	74%	74%
Gross Margin non-Durable goods %	72%	77%	77%	77%
Selling expenses %	-32%	-31%	-33%	-28%
Admin. expenses %	-19%	-12%	-17%	-11%
R&D expenses %	-26%	-30%	-31%	-28%
Items affecting comp.	-13	-	-36	-7
EBITDA (excl. items affecting comparability)	7	8	20	36
EBITDA (excl. items affecting comparability) %	11%	13%	11%	16%

Q4:

- ▶ **Q4 OPEX** 56 MSEK (44). Increase of 12 MSEK.
- ▶ Items affecting comp. of 13 MSEK (-).

FULL YEAR:

- ▶ **Full year OPEX** 179 MSK (159). Increase of 20 MSEK.
- ▶ Items affecting comp. of 36 MSEK (7).

Items affecting comparability are cost provisions for share-based bonus programs for employees outside Sweden, reorganization costs and M&A/integration costs.

▶ **Adj. EBITDA Q4: 11 %**

▶ **Adj. EBITDA FY: 11 %**

CASH FLOW

	MSEK	Q4		Full Year	
		2020	2019	2020	2019
Operating cash flow before changes in working capital		-2	10	-8	31
Working Capital	Change in inventories	1	2	-14	-8
	Change in trade receivables	8	-6	21	-1
	Change in trade payables	-30	-13	-11	7
	Operating cash flow	-22	-7	-12	30
	Investing activities	-222	-26	-267	-84
	Financing activities	-2	-1	483	26
	Cash flow for the period	-246	-34	204	-29
		0	0	0	0
	Cash at beginning of period	608	198	160	187
	FX effects in Cash	-8	-3	-10	2
	Cash at period end	354	160	354	160

Q4:

- ▶ Operating Cash flow before changes in WC impacted by lower gross profit and integration costs.
- ▶ WC effect -20 MSEK, net, mainly due to payment of acquired payables in Organ Assist and integration costs
- ▶ 19 MSEK invested in R&D projects
- ▶ Acquisition of Organ Assist net effect on cash flow -201 MSEK

FULL YEAR:

- ▶ Operating Cash flow before changes in WC impacted by and lower gross profit and M&A costs.
- ▶ WC effect -5 MSEK, net
- ▶ 60 MSEK invested in R&D projects
- ▶ 500 MSEK raised through directed share issue

▶ Cash at period end: **354 MSEK**

BALANCE SHEET

MSEK	Dec 31	
	2020	2019
ASSETS		
Goodwill	224	66
Capitalized development expenditure	394	266
Other intangible fixed assets	7	6
Fixed assets	21	24
Financial assets	41	13
Total non-current assets	687	375
Inventories	59	44
Current receivables	50	56
Cash and cash equivalents	354	160
Total current assets	463	260
Total assets	1,150	635
EQUITY AND LIABILITIES		
Equity	1,008	578
Long-term liabilities	67	4
Short-term non-interest-bearing liabilities	75	53
Total shareholders' equity and liabilities	1,150	635

MSEK	Dec 31	
	2020	2019
Equity/assets ratio %	88%	91%
Intangible assets/assets ratio %	54%	53%

COMMENTS:

- ▶ PPA finalized in Q4
- ▶ Goodwill 166 MSEK
- ▶ Amortization of capitalized R&D starts once regulatory approval is received
- ▶ Provision for milestone payment explains increase of long-term liabilities

Purchase Price Allocation - Organ Assist acquisition, 1 Oct (MSEK)

PURCHASE PRICE	Fair Value
Paid in cash	201
Conditional milestone payment	42
Total	243
ACQUIRED ASSETS	
Kidney R&D project	48
Liver R&D project	36
Other assets and liabilities	-7
	77
Goodwill	166
Total	243

2020

IN REVIEW

HIGHLIGHTS 2020



First patient transplanted in the European **Heart Preservation** study



Kidney Transport device publication in **The Lancet**



XVIVO Perfusion **acquired Organ Assist B.V.**

New **Strategy 2025** was adopted and **new management and organisation** in place



First patient included in the extended **PrimECC®**-study



Heart Preservation study published in **Nature Communications**



The ready- and easy-to-use **PERFADEX® Plus** with Click Port **launched globally**

AN ALL-ORGAN COMPANY



1. First global all organ company

- ▶ Through the acquisition of Organ Assist, XVIVO Perfusion deliver advanced solutions for transplantation of all organs



2. World leading in Lung and Liver transplantation with established network in thoracic and abdominal surgery

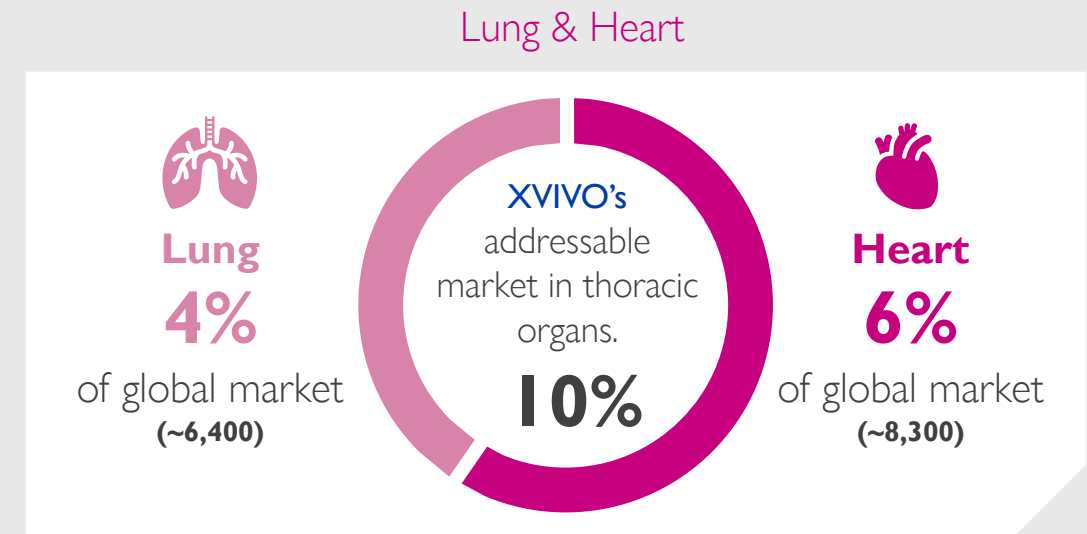
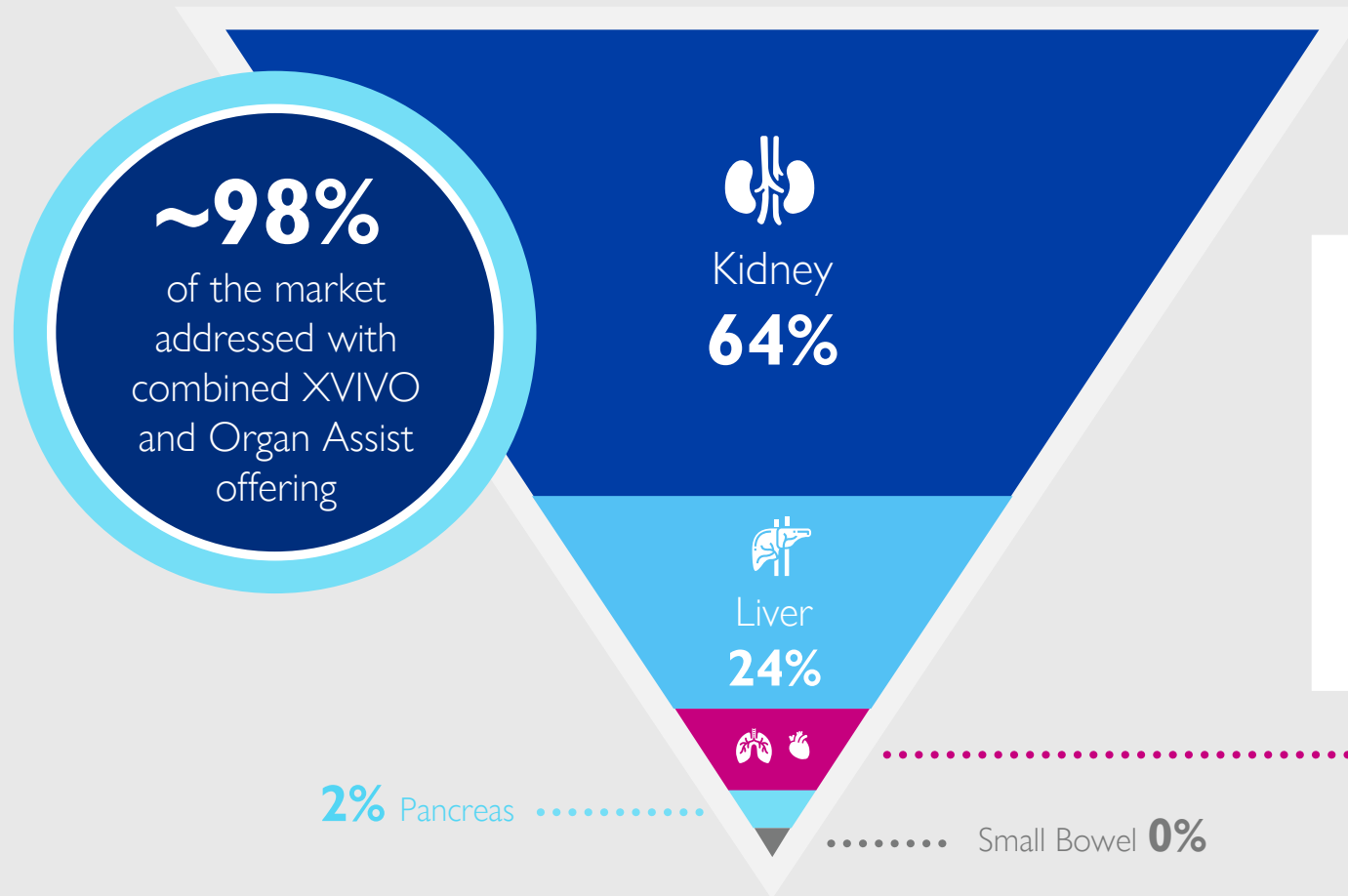
- ▶ XVIVO Perfusion is a strong global brand and market leader in liver and lung transplantation



3. Experts in advanced solutions for transplantation

- ▶ Together with world leading key opinion leaders in the transplantation field, we develop the optimal solutions for utilizing more organs for transplant

XVIVO - AN ALL-ORGAN COMPANY



OUR EXTENDED PRODUCT PORTFOLIO

Warm perfusion – New technology



XPS™
The comprehensive EVLP platform



XVIVO LS™ & XVIVO DISPOSABLE LUNG SET™
Provides a method for evaluating lungs by EVLP



XPS DISPOSABLE LUNG KIT™
Convenient, reliable, sterile accessories

Accessories



STEEN SOLUTION™
For reliable objective assessment of “marginal” and rejected lungs



XVIVO ORGAN CHAMBER™
Single use, sterile disposable container



XVIVO LUNG CANNULA SET™
Single use, sterile disposable product

Cold preservation



PERFADEX PLUS®
The gold standard in lung preservation made ready-to-use



XVIVO SILICONE TUBING SET™
For perfusion and donor lung procurement

Organ Assist's product line

DONOR ASSIST



LIVER ASSIST



LUNG ASSIST



KIDNEY TRANSPORT
First generation Kidney Transport device is CE-marked



KIDNEY ASSIST

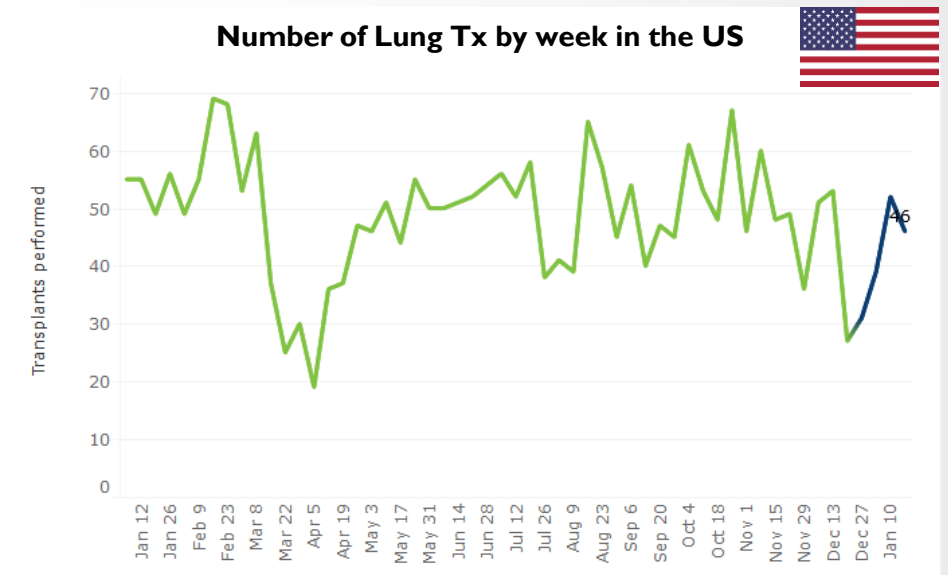


The combination of XVIVO and Organ Assist technology can better preserve and evaluate organs to increase the number of organs used for transplantation

COVID-19 IMPACT ON TRANSPLANT ACTIVITY

JANUARY-DECEMBER 2020:

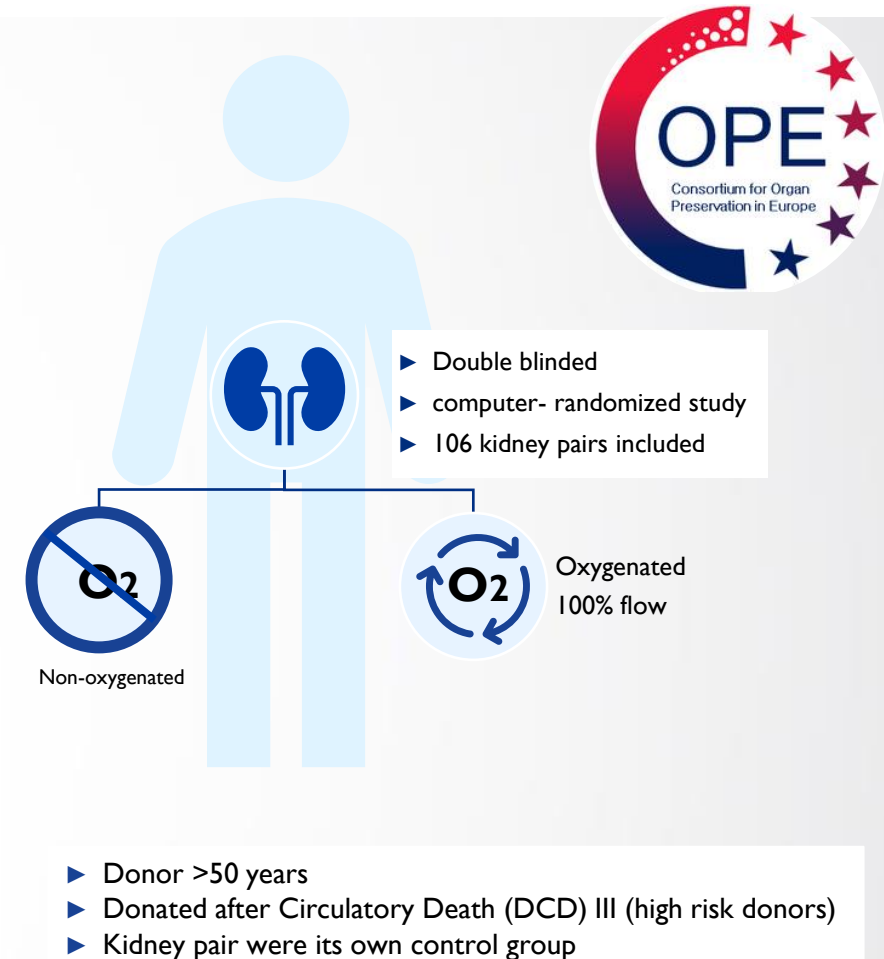
- ▶ The COVID-19 pandemic resulted in a significant reduction in overall organ transplantation procedures globally
- ▶ Continued recovery during Q3-Q4, but the COVID-19 “second wave” has resulted in lower Tx activity globally vs. last year (LY)
 - ▶ Several hospitals have COVID-19 precautions with reduced ICU capacity (treating donors, post Tx and COVID patients)
 - ▶ Number of available donors is temporarily lower
- ▶ Lung Tx activity in US -6% vs LY
- ▶ In Europe and Pacific Lung Tx -10% to -30% vs LY (local variations apply)



INTERESTING FINDINGS IN THE LANCET STUDY

MULTICENTRE STUDY COPE CONSORTIUM

- ▶ The group treated with **100% oxygen** showed **significant better results** compared to the control group:
 - ▶ Complete loss of graft function reduced from **10%** to **3%**
 - ▶ Reduced acute rejection with **48%**
 - ▶ Significantly improved renal function
- ▶ Authors suggests that using **100% oxygen** with full flow **will reduce**:
 - ▶ Severe complications
 - ▶ Additional diagnostic procedures
 - ▶ Hospital re-admission
 - ▶ Costs for chronic dialysis



CLINICAL TRIALS UPDATE

Heart Preservation (NIHP*) device to extend preservation time:

- ▶ 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
- ▶ Investigator driven Heart Preservation (NIHP) study in Sweden including patients to clinically document products and protocol
- ▶ In the EU regulatory study, inclusion has started at four out of nine centers. One additional center was added and trained during Q4
- ▶ In the US, preparations to start the study are on-going

PrimECC®:

- ▶ PrimECC® is patented, CE-marked and a study with 80 patients performed
- ▶ 13 patients have to date, been included in the extended PrimECC® study. Total inclusion will be 366 patients.



OUTLOOK 2021

STRATEGY PLAN 2020-2025

BUILD A HIGH PERFORMING TEAM

- ▶ Leadership team in place including new CCO, Head of R&D, COO, CIPO and CMO
- ▶ Focus on execution of top strategic priorities for company and functions to ensure successful commercialization and optimized time to market

BECOME AN ALL ORGAN COMPANY

- ▶ Secure successful combinations of solutions and machines to build a strong offering in transportation and evaluation systems – for all major organ areas (lungs, heart, kidney and liver)

COMMERCIAL EXCELLENCE

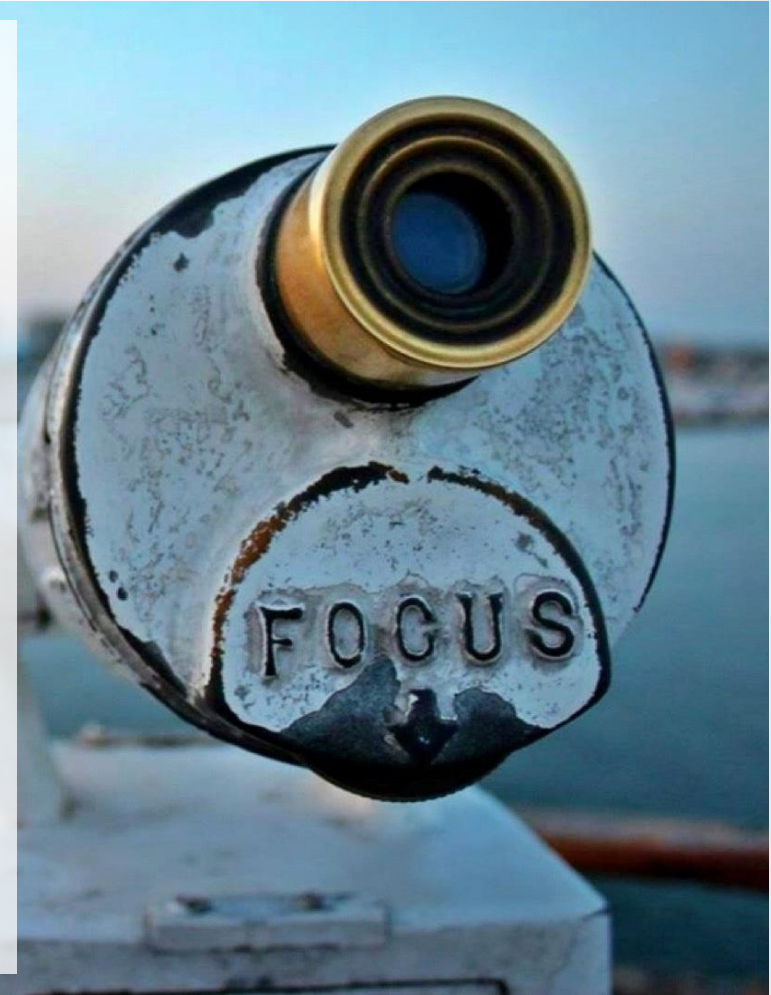
- ▶ New incentive model for key account managers, geographical expansion, key account management recruitment, strategic pricing and development of professional sales tools to maximize customer loyalty and sales

CUSTOMER DRIVEN INNOVATION

- ▶ Leverage the perceived R&D leadership, while implementing customer insight driven processes to reduce time to market and improved customer experience

OPERATIONS EXCELLENCE

- ▶ Best in class supply chain and continued high customer service and satisfaction with increased focus on design for manufacturing and supplier evaluation



OUTLOOK 2021 – FOCUS AREAS

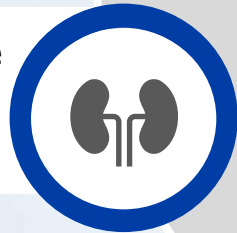
Extended EVLP machine offering
with two platforms (XPS + Lung Assist)



Integration of Organ Assist and selling
the full range of products, subject to
regulatory approvals



FDA approval and CE-mark for the
Kidney transport device and
commercial launch in EU and US



Heart Preservation Project
with focus on initiating studies in
US and Australia



Continuous work on our **pricing model**



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