

# Q4 Financials - at a glance

**Net Sales** 

## SEK 132 Million

Sales growth

## **Total 53%**

- Organic growth 27 %
- Acquired growth 7 %
- Currency effect 19 %

EBITDA (adj)

15 %



### **Thoracic**

Net Sales

Gross margin

SEK 88 million

Disposables 85%

Local currency growth

Disposable sales

+22%



### **Abdominal**

Net Sales

Gross margin

SEK 27 million

Disposables 54%

Disposable sales

+37%



#### Services

Net Sales

**Gross margin** 

SEK 16 million

Recoveries 47%

+44%

Case revenue



# 2022 Financials - Full year

**Net Sales** 

## **SEK 415 Million**

Sales growth

## **Total 61%**

- Organic growth 30 %
- Acquired growth 15 %
- Currency effect 16 %

EBITDA (adj)

14 %



### **Thoracic**

• Net Sales SEK 296 million

**Gross margin** Dis

Disposables 84%

growth

Local currency

Disposable sales

+26%



### **Abdominal**

Net Sales

Gross margin

SEK 71 million

Disposables 54%

Disposable sales

+34%



#### Services

Net Sales

Gross margin

SEK 48 million

Recoveries 49%

Case revenue

+39%



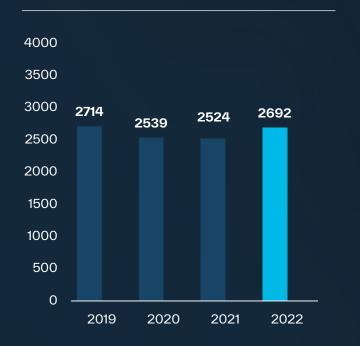


## Transplant recovery - US trend positive

### Number of lung tx (Q4)



### Number of lung tx (Full year)



# Tx activity All organs (2022 vs 2021)

	vs 2021 vs	2019
Lung	+7%	-1%
Heart	+8%	+16%
Liver	+3%	+19%
Kidney	+5%	+7%



# Kidney Assist Transport

## FDA 510(k) approval obtained in 2022

- Featured in the scientific journal The Lancet<sup>1</sup> in 2020
- Great interest at transplant congresses during 2022
- First devices placed at US clinics for user experience feedback
- Device manufacturing scale-up
- Launch in US and Europe expected to accelerate in Q1 2023



## MDR certifications obtained

## Strenghtened position in Europe

- In 2022 both Kidney Assist Transport, Kidney Assist and Liver Assist have obtained MDR certification
  - Secures future sales and market leading position on the European Market
- 2023 ambition is to obtain MDR certification for the thoracic product portfolio









KIDNEY ASSIST TRANSPORT™



LIVER ASSIST™



## Liver Assist

## FDA Breakthrough Designation

- Liver Assist featured in the NEJM¹ in 2021 showing that oxygenated hypothermic perfusion of DCD donor livers before transplantation has a significant positive impact on post-transplant clinical outcomes
- Initial market feedback in the USA suggests strong interest in Liver Assist technology and the need for an alternative to currently available technologies
- XVIVO will pursue the PMA route for the Liver Assist in the USA



# Completion of Avionord M&P acquisition

#### Deal rationale



Secure and build Italy



Increase penetration of machine perfusion Increase revenue and margin per procedure



Option GISTO – transport device for static cold preservation of all organs

- Italian medical device distributor, service and logistics provider
- Revenue model based on price per procedure structure: disposables + services
- High margin business with high customer satisfaction
- Active in 15/22 liver transplant centres in Italy
- 20 25% machine perfusion penetration in Italy for abdominal
- Maximum purchase price EUR 12 million
- Integration off to a successful start, fully commercially integrated



# XVIVO Heart Technology

### Australia/ New Zealand Trial

- Last patient included during Q4 2022
- Successful transplant after record breaking out-of-body time achieved: 8h 47min
- Preliminary study data from first 20 patients featured in presentation at American Heart Association Nov 2022
  - Mean transport time 7h
  - Survival 100%
  - 0% Left ventricular Primary Graft Dysfunction (PGD)\*
- Presentation on the Australian experience with the XVIVO heart technology from Dr. David McGiffen at XVIVO CMD - Prof. of Cardiothoracic Surgery and Transplantation at Alfred Health, Melbourne Australia
- 6 compassionate use cases at 4 centers since mid-December





Ground-breaking Xenotransplant

## First successful transplant from pig to human

- Transplant took place in January, 2022
- University of Maryland School of Medicine, US
- XVIVO supports two leading research teams (Maryland, US and Munich, Germany)
- High interest from other centers to start Xeno in Heart and Kidney
- Xenotransplantation could help to reduce the organ shortage, XVIVOs innovative technology is crucial in driving research forward





## Status in clinical trials

### European Heart preservation trial

- All planned 15 centers active across 8 countries
- Approx. 80% of patients enrolled

Target: Commercial launch Q1 2024

### US Heart preservation trial

- IDE-application submitted and interaction with FDA on-going
- High impact/volume transplant centers enrolled and site qualified
- Study expected to start during 2023

### ANZ Heart preservation trial

- Last patient enrolled in Q4 2022
- Initial study data from first 20 patients as featured presentation at American Heart Association Nov 2022
- High interest for compassionate use in Australia/New Zeeland

Target: Commercial launch Q1 2024



# Net sales and results in Q4

Total Sales growth

53%

	Oct-Dec	Oct-Dec	Full Year
SEK Million	2022	2021	2022
Net sales	132	86	415
Sales growth, %	53 %	42%	61 %
Whereof organic growth, %	27 %	32 %	30 %
Gross profit	95	63	297
Gross margin, %	72 %	73 %	72 %
EBIT (adj)	9	1	14
EBIT, % (adj)	6 %	2 %	3 %
EBITDA (adj)	20	10	56
EBITDA (adj), %	15 %	11 %	14 %

<sup>1</sup>Adjusted for effect from cost provision attributable to cash-based incentive program for employees outside of Sweden and integration costs. Net adjustment totals SEK -6,2 (-9,7) million for the quarter and -7,9 (-15,8) for the period (YTD).



# Thoracic - Q4 Highlights

**Net Sales** 

SEK 88 million (59)

Organic growth in local currency

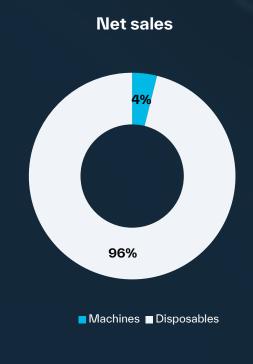
26 %

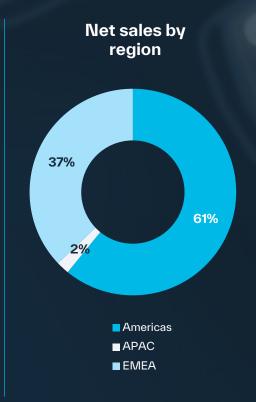
Gross margin disposables

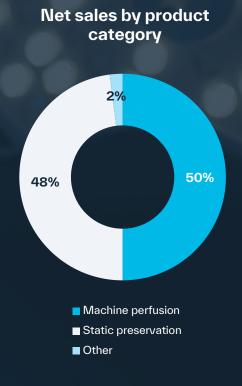
85 % (83)

XPS machines delivered

1









# Abdominal - Q4 Highlights

**Net Sales** 

SEK 27 million (21)

Organic growth in local currency

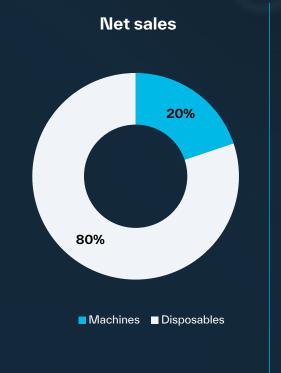
27 % (29)

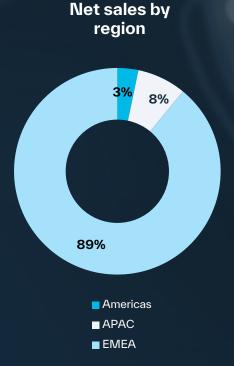
Gross margin disposables

54 % (55)

Organic growth disposables (%)

37



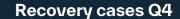








# Services -Q4 Highlights





#### **Net Sales Q4**



Full Year 2022

Net Sales (SEK)

48m

Sales growth

39%

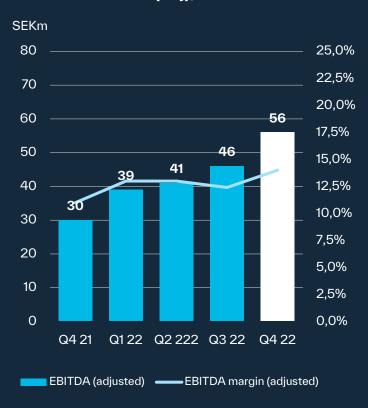
Recovery cases

495

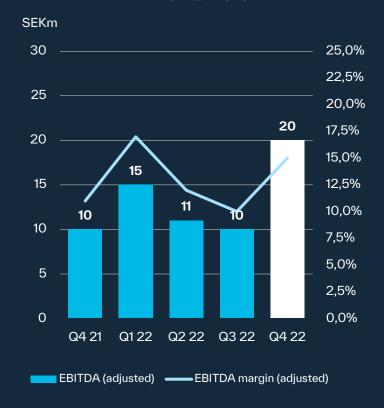


## EBITDA

### EBITDA (adj), R12 months



### EBITDA (adj), by quarter





#### **Comments**

- R12 Trend continues with increased EBITDA
- Increased gross profit/gross margin in Q4 and YTD
- Investments in organisation to support future growth

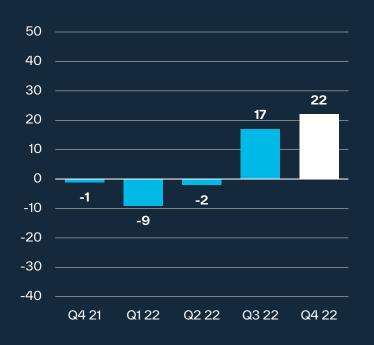


## Financial position and cash flow (Dec 31, 2022)

#### **Q4** financials

- Cash flow from operating activities SEK +22 million (-1)
- Investments SEK -77 million (-125)
- Total Cash flow SEK-58 million (111)
- Cash position Dec 31: SEK 247 million (398)
- Equity/assets ratio of 83 % (83)

## Cash flow from operating activities (SEK million)



#### **Comments Q4**

- Strong cash flow from Operating activities
  - Increased sales and EBITDA Q3/Q4
  - Reduced working capital

#### Investments

### **Avionord acquisition**

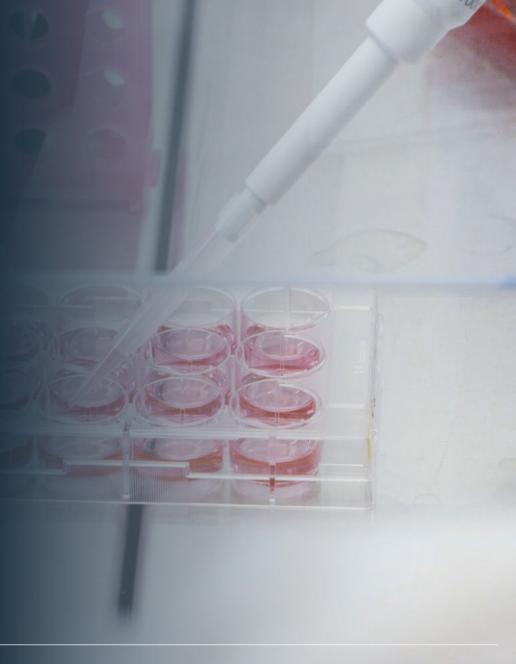
- Initial purchase price cash part: SEK 42 million paid in Q4
- Additional purchase price of SEK 25 million expected to be paid in Q2 2023





## Long term outlook

- The demand for transplants are x 10 of today's supply
- Sales value of machine perfusion vs cold static storage is ~x 10
- Machine perfusion has proven to increase the number of organs used for transplantation
- XVIVO has unique, innovative and world leading products on the market or in the R&D pipeline
- Strong MGMT team and organization in place



## Outlook 2023

- Machine perfusion continued momentum through hub and service models
- Kidney Assist Transport Launch in the US and Europe
- Heart Prepare for commercial launch Europe and ANZ.
   Start PMA study in the US
- Liver Prepare for trial application submission in the US
- Continued price increases and strengthened gross margins



