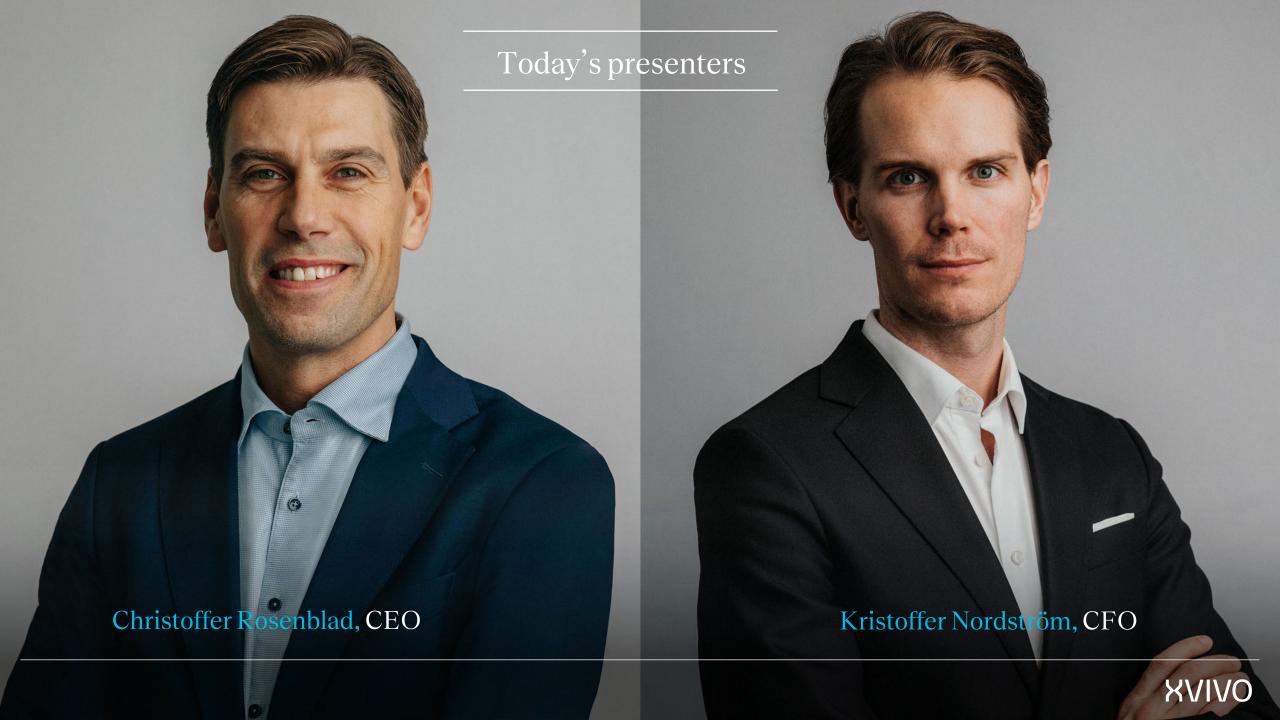
# **XVIVO**

# Interim report Q2 2023





# Q2 Financials - at a glance

**Net Sales** 

## SEK 155 Million

Sales growth

## **Total 64%**

- Organic growth 46 %
- Acquired growth 6 %
- Currency effect 12 %

EBITDA (adj)

19%



#### **Thoracic**

 Net Sales SEK 104 million

**Gross margin** 

Disposables 84%

+47%

Disposable sales

Organic Growth

Disposable sales



#### **Abdominal**

Net Sales

**Gross margin** 

SEK 30 million

+40% Disposables 70%



**Net Sales** 

**Gross margin** 

SEK 20 million

Recoveries 49%

+79%

Case revenue



# YTD Financials - at a glance

**Net Sales** 

## SEK 295 Million

Sales growth

## **Total 58%**

- Organic growth 39 %
- Acquired growth 6 %
- Currency effect 13 %

EBITDA (adj)

18 %



#### **Thoracic**

• Net Sales SEK 195 million

Gross margin

Disposables 85%

Organic Growth

Disposable sales

+40%



#### **Abdominal**

Net Sales

• Gross margin

SEK 61 million

Disposables 67%

Disposable sales

+56%



#### Services

Net Sales

Gross margin

SEK 39 million

Recoveries 48%

+77%

Case revenue





# Positive momentum for XVIVO paradigm changing heart technology

#### Patient inclusion completed in European heart trial

- √ 202 patients enrolled across 15 leading transplant centers in 8 European countries
- ✓ Strong feedback from leading transplant surgeons
- √ Targeting commercial launch first half 2024

#### Great continued interest in Australia/New Zeeland

- About 25 % market penetration YTD
- 4 out of 5 trial sites active via compassionate use. The 5<sup>th</sup> to come.



Positive momentum for XVIVO paradigm changing heart technology

#### IDE application approved by the US FDA

- Trial to include 141 patients
- Recommendation from FDA to include DCD inclusion criteria in study design
- Patient enrolment expected to start 2<sup>nd</sup> half 2023 –
   Pending final protocol approval including DCD inclusion criteria from US FDA
- High impact transplant centers engaged and trial sites qualified



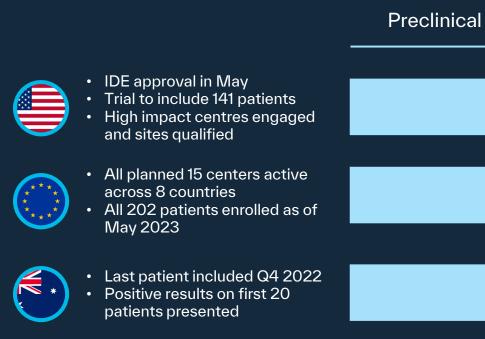
STAR Teams integration and commercia development

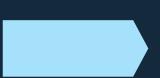
- Becoming the preferred partner in the transplant process
- Strengthened value proposition under one brand and one organisation
  - Associated one-time costs: 11m SEK in Q2, 11m SEK H2 2023
- Strategic collaboration with MTJ Aviation to guarantee predictable and reliable transportation
  - Reducing logistical complexity and lowering transportation costs by co-locating surgical teams and aircrafts
  - Aircrafts dedicated to XVIVO organ procurement service at 3 primary hubs: NC, MI, FL





# Clinical Trial Status & Tentative Timeline





#### Finalize planning phase 2023

Clinical

Patient enrolment

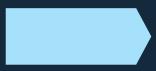
expected H2 2023\*

✓ Possibility to conduct US heart and liver trial simultaneously to accelerate time to market





- Breakthrough Device Designation by FDA
- Trial design and planning phase
- Investments in organization planned for 2023/2024





Market

Approval

Commercial launch

Commercial launch

Currently sold under

pending CE-mark.

special permit

target H1 2024\*\*

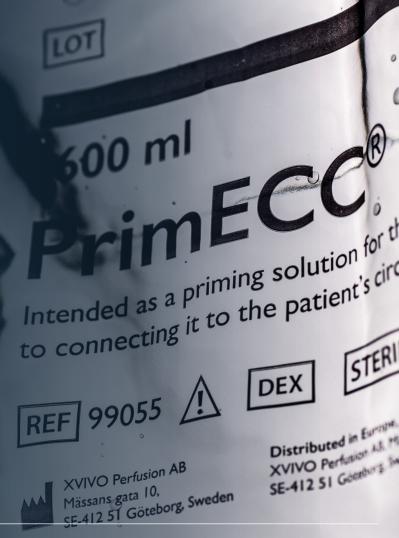
Regulatory

Review

1-year follow-up phase

# Further patient inclusion in PrimECC study closed – strategic options to be evaluated

- PrimECC is a solution used to prime the heart-lung machine before heart-surgery
- Study initiated in 2020. Further patient inclusion closed due to pace of patient recruitment below expectations
- Study data will be analyzed and strategic opportunities evaluated. Future pathway to be decided within 6-months\*
- Decision has no impact on 2027 financial targets





# Net sales and results in Q2

Total Sales growth Q2 64%

	Apr-Jun	Apr-Jun	YTD	YTD
SEK Million	2023	2022	2023	2022
Net sales	155	94	295	187
Sales growth, %	64 %	28 %	58 %	59 %
Whereof organic growth, %	46 %	16 %	40 %	30 %
Gross profit	115	67	220	133
Gross margin, %	<b>75</b> %	<b>72</b> %	<b>75</b> %	71 %
EBIT (adj)	15	4	28	6
EBIT, % (adj)	10 %	1%	9 %	3 %
EBITDA (adj)	29	11	53	27
EBITDA (adj), %	19 %	12 %	18 %	14 %

Adj: Adjusted for effect from integration costs. Net adjustment totals SEK 11 (-3) million for the quarter.



# Thoracic - Q2 Highlights

**Net Sales** 

**SEK 105 million (69)** 

Organic growth disposables

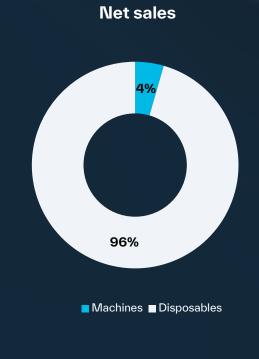
47 % (24 %)

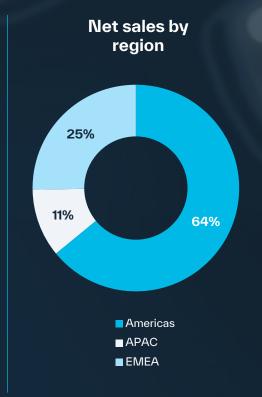
Gross margin disposables

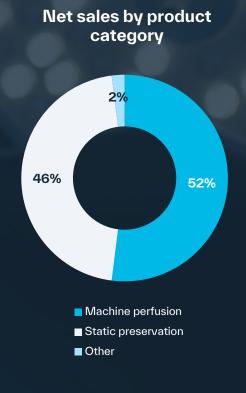
84 % (82)

XPS machines delivered

1









# Abdominal - Q2 Highlights

**Net Sales** 

SEK 30 million (15)

Organic growth disposables

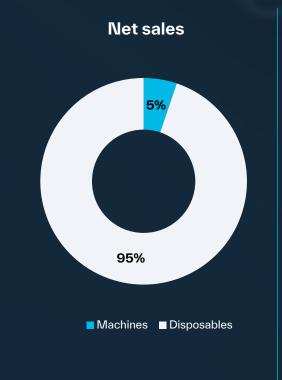
40 % (93)

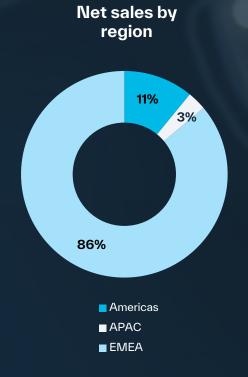
Gross margin disposables

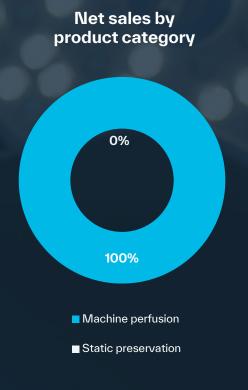
70 % (56)

Total growth disposables, local currencies (%)

**79** 





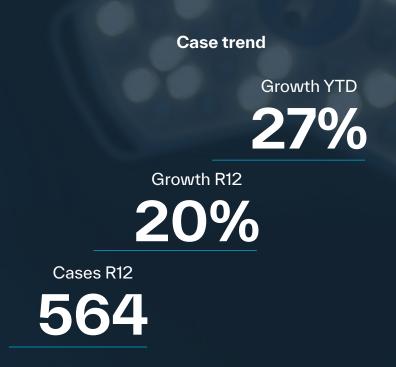




# Services -Q2 Highlights



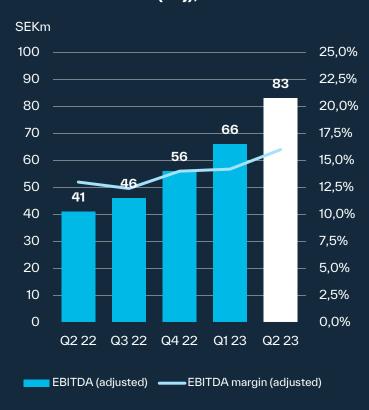






## EBITDA

#### EBITDA (adj), R12 months



#### EBITDA (adj), by quarter



# EBITDA (adj) Q2 19%

#### **Comments Q2**

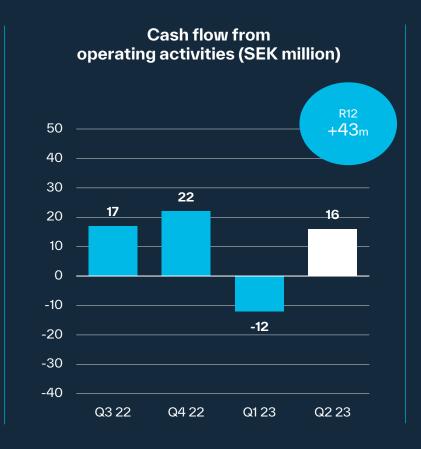
- R12 Trend continues with increased EBITDA
- Primarily driven by increased gross profit
- Continous investments in organisation to support future growth



# Financial position and cash flow (Jun 30, 2023)

#### **Q2** financials

- Cash flow from operating activities SEK +16 million (-2)
- Investments SEK -47 million (-34)
- Total Cash flow SEK-34 million (-36)
- Cash position Jun 30: SEK 171 million (318)
- Equity/assets ratio of 84 % (85)



#### **Comments Q2**

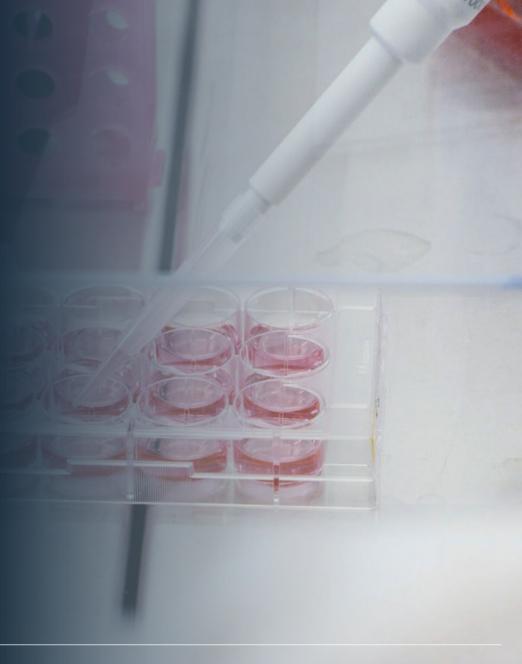
- Positive operating cashflow from strenghtened EBITDA, despite further spend on inventories
- M&A related payments of -18 million related to previous Avionord and STAR aquisitions





# 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



# Outlook 2023

- Machine perfusion continued momentum through hub and service models
- Kidney Assist Transport Continued introduction in the US and Europe
- Project to scale up production x 10
- Heart Prepare for commercial launch Europe and ANZ.
   Start PMA trial in the US
- Liver Prepare for trial application submission in the US



# Nobody should die waiting for a new organ

