

XVIVO

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# Interim report Oct – Dec 2021

Telephone conference, January 27, 2022

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Today's presenters

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A portrait of Dag Andersson, an older man with grey hair and glasses, wearing a dark blue suit jacket over a white shirt. He has his arms crossed and is looking directly at the camera.

Dag Andersson CEO

A portrait of Kristoffer Nordström, a younger man with dark hair, wearing a dark suit jacket over a white shirt. He has his arms crossed and is looking directly at the camera.

Kristoffer Nordström CFO

# Highlights in Q4

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## Financials

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- **Total sales** amounted to SEK 86 million (60), with organic growth of 32% and acquired growth of 10%
- Sales record in all Business Areas:
  - **Thoracic sales** amounted to SEK 59 million (44), with organic growth of 33%
  - **Abdominal sales** totaled SEK 21 million (17), with organic growth of 29%
  - **Services**<sup>1</sup> provided SEK 6 million (-) in sales for the period November-December
- **Gross margin** increased, mainly due to higher prices to customers and economies of scale from increased sales
  - Thoracic gross margin amounted to 82% (76)
  - Abdominal amounted to 54% (48)
- **EBITDA (adjusted)** 11 % (11)
  - Including non-recurring items in M&S of SEK 4 million

1. Services is the new Business area holding STAR Teams. Included in Q4 result with two months (Nov-Dec).

# Highlights in Q4

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## Significant events during the quarter

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### Acquisition of STAR Teams

- XVIVO acquired 100 percent of the shares in the US organ recovery company STAR Teams
- STAR Teams is a pioneer within thoracic organ recovery in the US market – aiming to enter the abdominal market
- Purchase price of up to USD 26.36 million
  - Initial purchase price of USD 12.61 million
  - additional potential earn-out payment of up to USD 13.75 million

### New share issue - zero rebate

- The acquisition of STAR Teams was financed by a new share issue of SEK 250 million
- In addition to strong support from existing shareholders, several new Swedish and international institutional investors participated





# Highlights in Q4

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## Significant events during the quarter

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### Heart preservation record in Australia

- With XVIVO's heart preservation technology a donor heart could be kept alive for 7 hours and 18 minutes before being successfully transplanted.
- This means a record when using XVIVO's technology in a clinical trial.

### Accelerating business operations in Brazil

- XVIVO signed a partnership contract with Contatti Medical, market leader on Brazil's organ transplantation market

### North American organization strengthened

- Fredrik Dalborg appointed Managing Director North America
- Jaya Tiwari appointed Vice President Clinical and Regulatory Affairs for the US
- New office opened in Philadelphia (PA)

# Subsequent events Q1

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## KaT 510(k) clearance

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- On January 21, 2022, XVIVO obtained 510(k) approval by the FDA for marketing of Kidney Assist Transport on the US market
- US is the largest market with 18,700 kidney transplants from deceased donors in 2021
- Kidney Assist Transport is a transport device for kidney and the **only device on the market to offer hypothermic oxygenated perfusion** of kidneys
- The features of the technology were highlighted in the scientific journal The Lancet in November 2020<sup>1</sup>

1. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32411-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32411-9/fulltext)



# Subsequent events Q1

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## Xeno-transplant (pig to human)

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- On January 7, XVIVO's technology for heart preservation was used in the world's first ever successful pig to human heart xenotransplantation
- A team at the University of Maryland School of Medicine, US, performed the procedure
- XVIVO's technology stores and transports donated hearts in an optimized way, through non-ischemic heart preservation (NIHP)



# Transplant activity

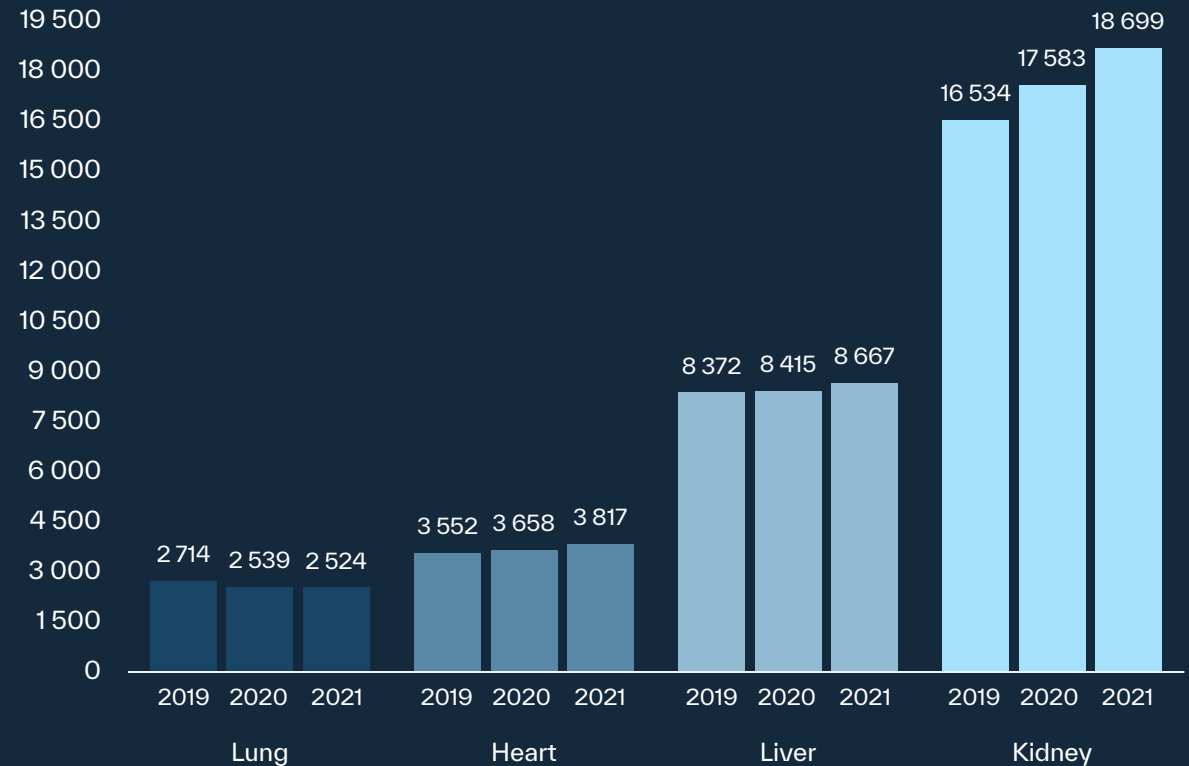


# 2021 US – all organ statistics

- Lung transplants
  - 2021 vs 2019 – 93.0%
  - 2021 vs 2020 – 99.4%
- Heart transplants
  - 2021 vs 2019 – 107.5%
  - 2021 vs 2020 – 104.3%
- Liver transplants<sup>1</sup>
  - 2021 vs 2019 – 103.5%
  - 2021 vs 2020 – 106.3%
- Kidney transplants<sup>1</sup>
  - 2021 vs 2019 – 113.1%
  - 2021 vs 2020 – 106.3%

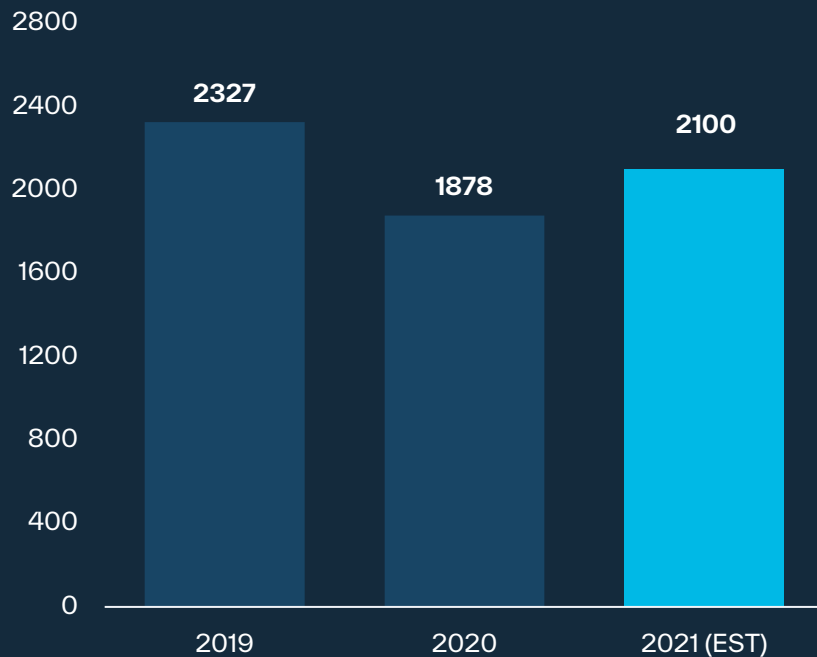
<sup>1</sup>Deceased Donor Transplants

## Number of transplants



# Lung transplants Europe

Number of transplants YTD (Europe)



- Covid impact on LTx varies from country to country

# Outlook 2022



# Outlook 2022

- Continued increase in transplant activity to meet 2026 target of 50 000 tx in US
- Kidney Assist Transport roll out in the US followed by Europe
- Continued increase in XPS/EVLP interest
- Price increase January 1 in Europe and US October 1
- Continued acceleration of clinical studies Europe/ANZ
- Initiation of US Heart trial
- STAR Teams to expand into Abdominal organ recovery

A woman with long brown hair, wearing a grey short-sleeved dress, is sitting in a blue office chair and smiling while talking to another person whose back is to the camera. The background is a blurred office environment with a whiteboard and papers.

# Financial Performance Q4

# Net sales and results in Q4

SEK Thousands	Oct-Dec 2021	Oct-Dec 2020	Change	Jan-Dec 2021
<b>Net sales</b>	<b>85,863</b>	<b>60,277</b>	<b>25,586</b>	<b>258,386</b>
Gross income	<b>62,959</b>	<b>41,357</b>	<b>21,602</b>	<b>188,121</b>
Gross margin, %	<b>73</b>	<b>69</b>	<b>4</b>	<b>73</b>
Operating income	<b>-8,300</b>	<b>-14,328</b>	<b>6,028</b>	<b>-18,498</b>
EBITDA	<b>-96</b>	<b>-6,506</b>	<b>6,410</b>	<b>13,759</b>
EBITDA, %	<b>-0</b>	<b>-11</b>	<b>11</b>	<b>5</b>
EBITDA (adjusted) <sup>1</sup>	<b>1,361</b>	<b>-1,050</b>	<b>2,411</b>	<b>-2716</b>
EBITDA (adjusted) <sup>1</sup> , %	<b>11</b>	<b>11</b>	<b>-</b>	<b>11</b>
Earnings per share <sup>2</sup> , SEK	<b>0.42</b>	<b>-0.68</b>	<b>1.1</b>	<b>0.28</b>
Organic growth in local currency, %	<b>32</b>	<b>-25</b>	<b>57</b>	<b>27</b>

<sup>1</sup>Adjusted for effect from cost provision attributable to cash-based incentive program for employees outside of Sweden, integration costs and cost relating to acquisition process. Net adjustment totals SEK -9.7 (-13.2) million for the quarter. Net adjustment for the period totals SEK -15.8 (-35.8) million.

<sup>2</sup>After dilution



# Thoracic – Q4 Highlights

Net Sales

**SEK 59 million (44)**

Gross margin

**82% (76)**

Gross margin non-durable goods

**83% (80)**

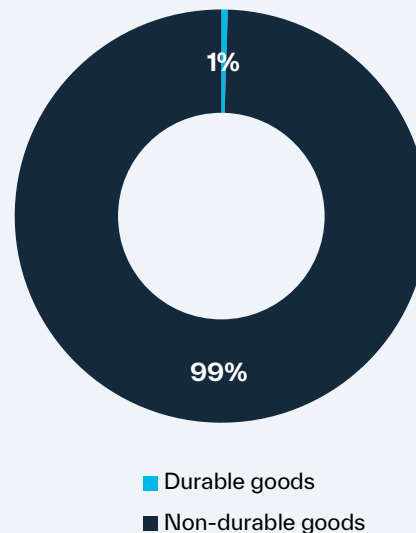
Gross margin durable goods

**7% (18)**

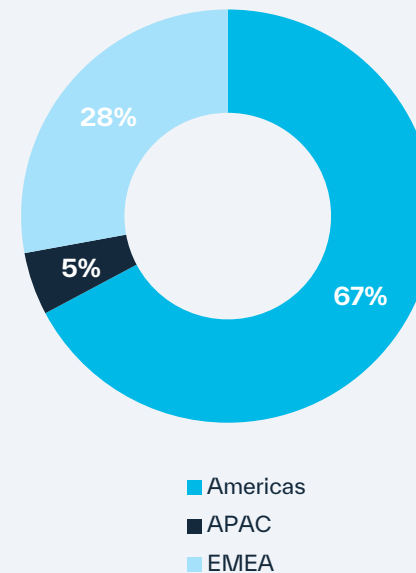
Organic growth in local currency

**33% (-)**

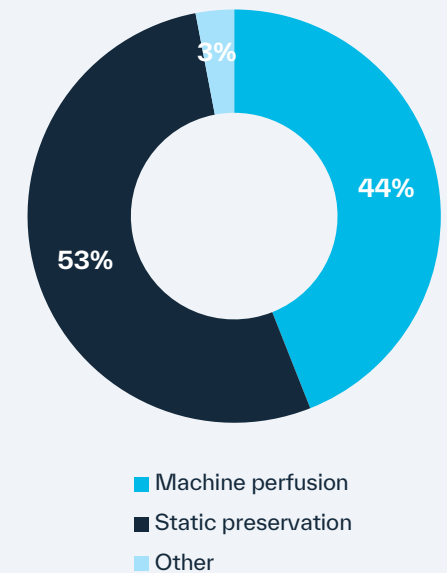
Net sales by  
segment (Q4)



Net sales by  
region (Q4)



Net sales by product  
category (Q4)



# Abdominal – Q4 Highlights

Net Sales

**SEK 21 million (17)**

Gross margin

**54% (48)**

Gross margin non-durable goods

**55% (50)**

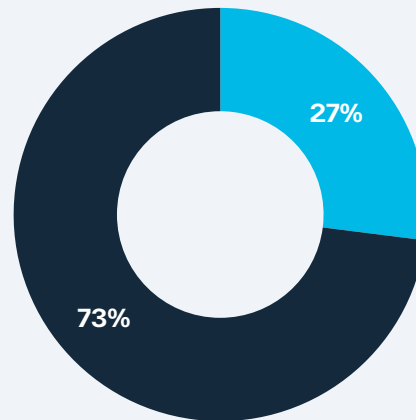
Gross margin durable goods

**50% (41)**

Organic growth in local currency

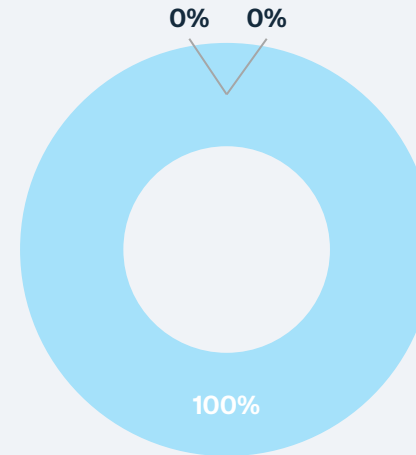
**29% (-)**

Net sales by  
segment (Q4)



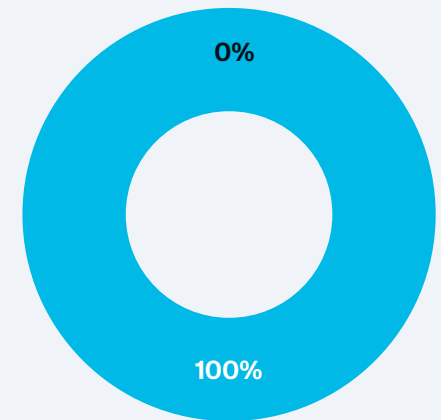
■ Durable goods  
■ Non-durable goods

Net sales by  
region (Q4)



■ Americas  
■ APAC  
■ EMEA

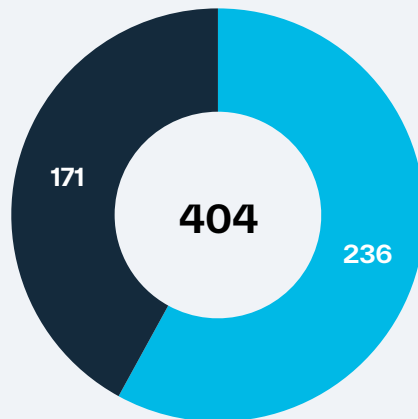
Net sales by  
product category (Q4)



■ Machine perfusion  
■ Static preservation  
■ Other

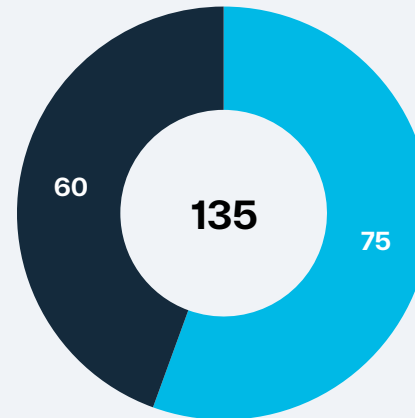
# Services – 2021 and Q4 Highlights

Organs recovered 2021



■ Hearts ■ Lungs

Organs recovered Q4



■ Hearts ■ Lungs

Net Sales (SEK)

**6m**

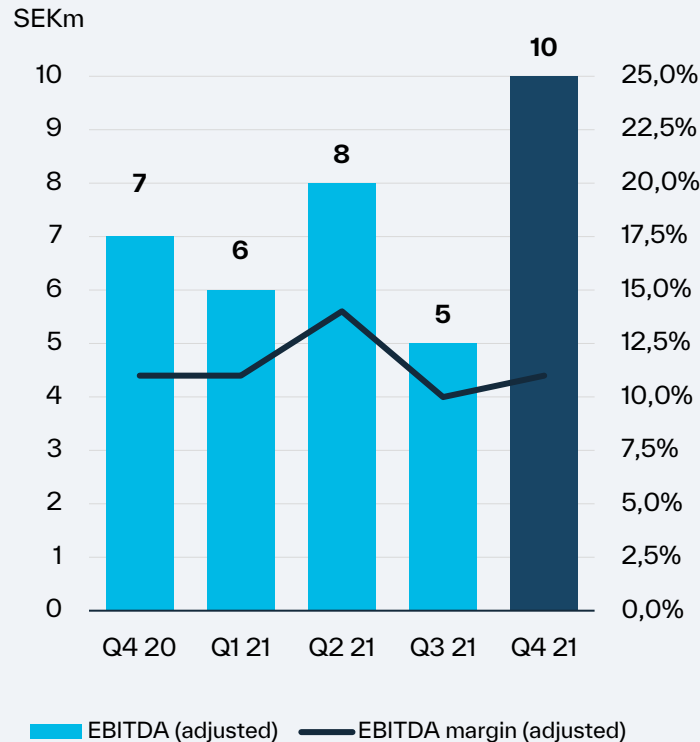
EBITDA

**25%**

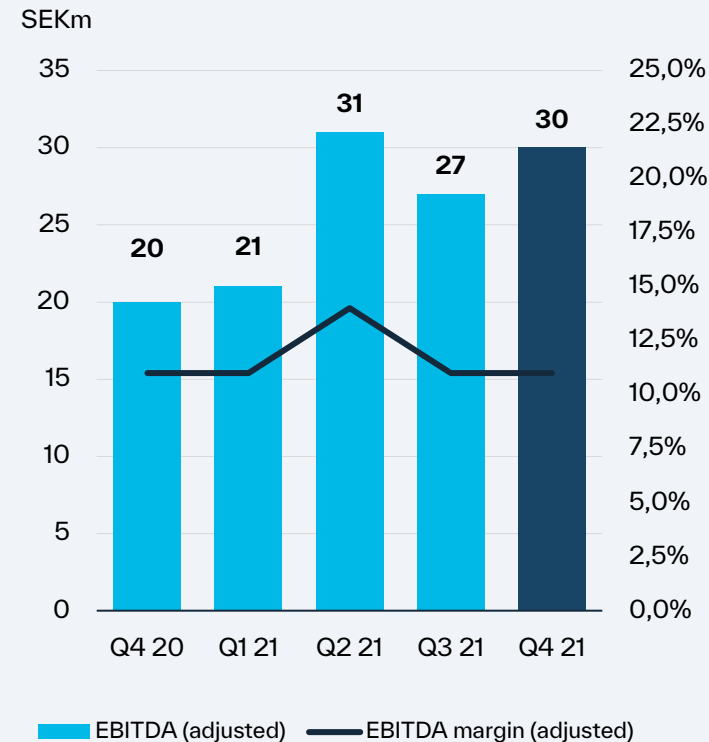


# EBITDA

**EBITDA (adjusted),  
by quarter**



**EBITDA (adjusted),  
rolling 12 months**

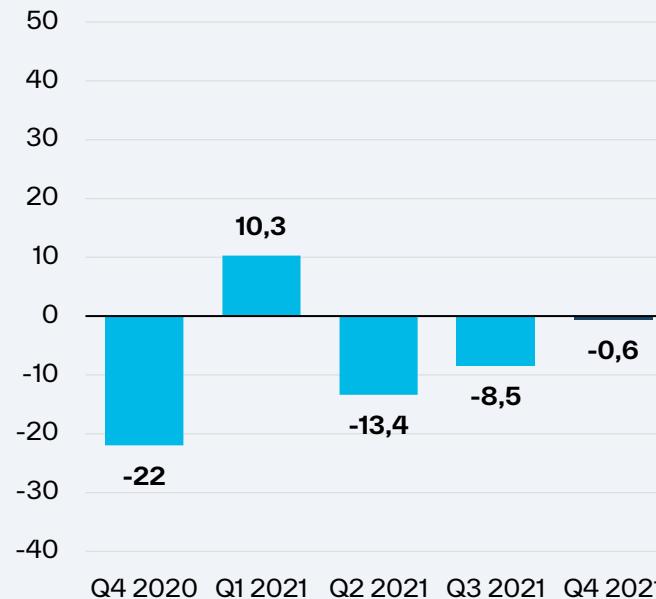


- Q4 SEK 10 million (7), 11% (11)
- Adj. for one-time costs: SEK 9.7 million
- EBITDA Q4 includes increased costs for M&S, non recurring 4 MSEK
- R12 SEK 30 million (20), 11% (11)

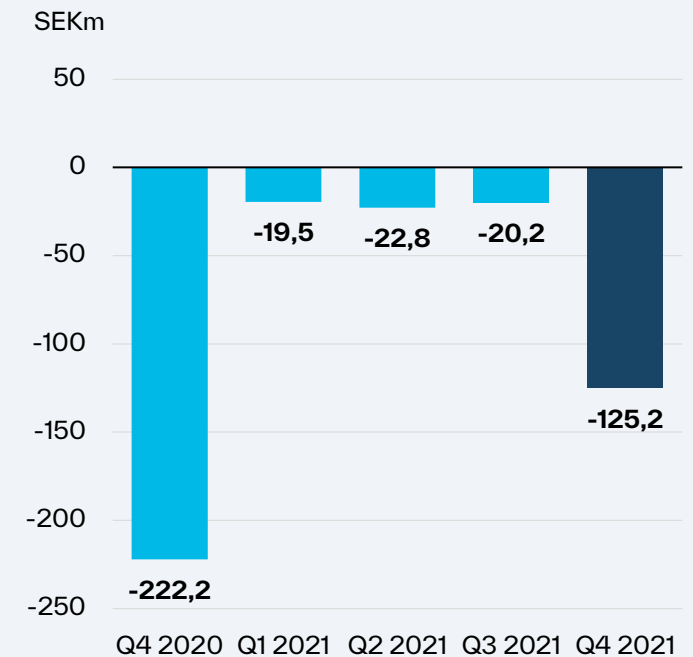
# Financial position and cash flow (Dec 31, 2021)

- Cash flow from operating activities SEK -0.6 million (-22)
  - $\Delta$ NWC SEK -10 million (10)
  - Total Cash flow in Q4 SEK 111 million (-246)
  - Cash by end Q4 SEK 399 million (354)
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- Total long-term liabilities SEK 153 million (68)
  - Total assets SEK 1,542 million (1,150) and equity SEK 1,285 million (1,008), corresponding to an equity/assets ratio of 83% (88)

Cash flow from operating activities



Cash flow from investing activities



# Financials 2021 – Full year

SEK Thousands	2021	2020	
<b>Net sales</b>	<b>258,386</b>	<b>179,861</b>	<b>+44 %</b>
Gross margin, %	73	74	
Organic growth in local currency, %	27	-24	
Acquired growth, %	22	7	
EBITDA	13,759	-15,637	
EBITDA (adjusted) <sup>1</sup>	29,541	20,172	
EBITDA (adjusted) <sup>1</sup> , %	11	11	

Organic growth in  
local currency

27%

Accuired growth

22%

<sup>1</sup>Adjusted for effect from cost provision attributable to cash-based incentive program for employees outside of Sweden, integration costs and cost relating to acquisition process. Net adjustment totals SEK 9.7 (13.2) million for the quarter. Net adjustment for the period totals SEK 15.8 (35.8) million.

A close-up, slightly blurred photograph of two women. The woman on the left is in profile, smiling and looking towards the right. The woman on the right is also in profile, looking towards the left, with her hand near her face. The background is out of focus, showing a wooden beam and a white wall.

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# R&D pipeline

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# Progress in clinical trials

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## European Heart preservation trial

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- 9 centers have been fully activated
- In total, 13-15 centers will participate

**Target:** Last patient in end 2022 / Commercial launch Q1 2024

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## ANZ Heart preservation trial

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- 7 hours and 18 minutes non-ischemic preservation record announced in Q3
- 2 centers have been fully activated

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## US Heart preservation trial

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- FDA discussions ongoing
- Aim to start the trial towards summer 2022

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## PrimECC

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1 center is currently including patients, Sahlgrenska Hospital, SE and another center, Dresden, Germany, was fully activated in January 2022.

- Ethics committee applications submitted to Rikshospitalet in Oslo, NO and Rigshospitalet in Copenhagen, DK.
- Inclusion ongoing with additional German centers

**Target:** Clinical study report finalized in Q2 2023 to support MDR submission



# Summary

# Summary

- Year ending on a high!
- Strong Q4 with growth in all business areas
- Good momentum for EVLP
- Kidney Assist transport US launch
- Continued focus on price increases
- STAR Teams doubled the number of organ recoveries
- Continued progress in clinical trials
- Management Team reinforced



Our vision

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Nobody should  
die waiting for  
a new organ

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