

XVIVO

Interim report Jan – Jun 2021

Telephone conference, July 13, 2021



Today's presenters

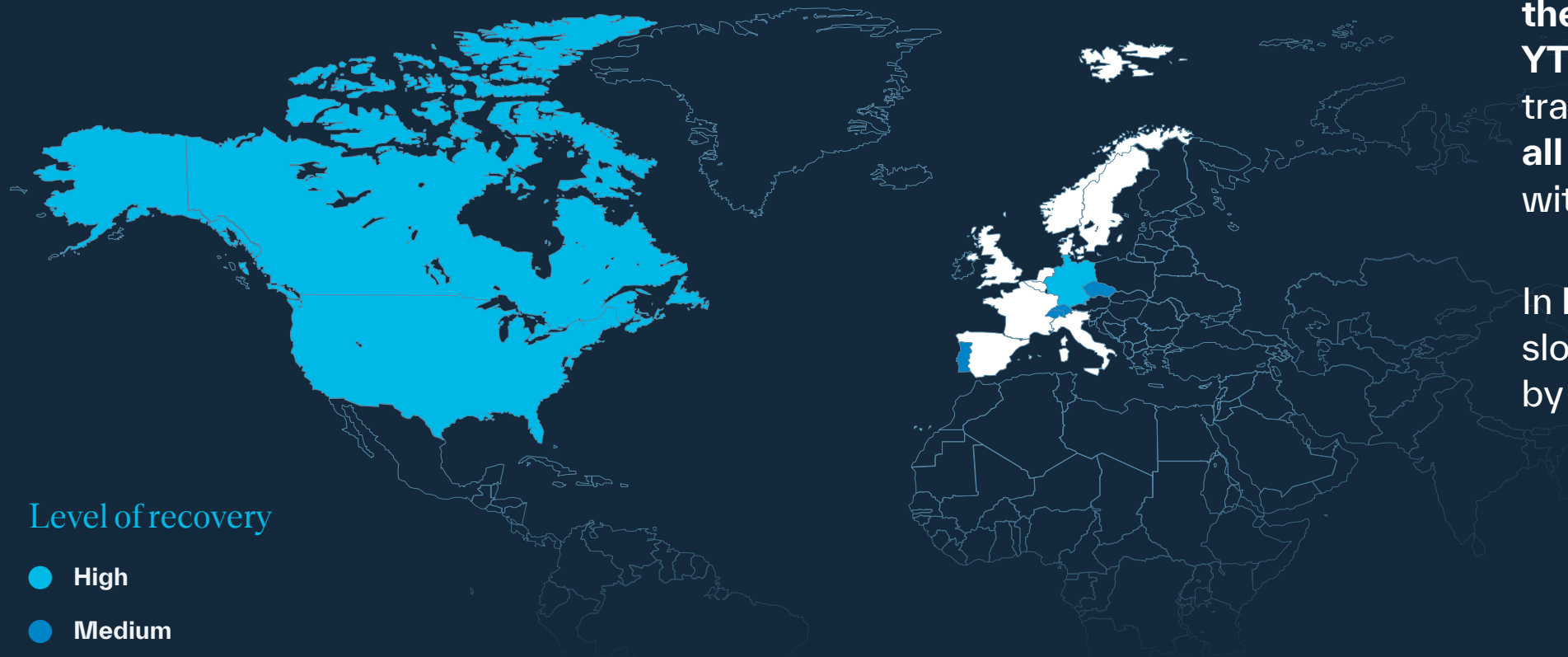
A portrait of Dag Andersson, an older man with grey hair and glasses, wearing a dark blue suit jacket over a white shirt. He has his arms crossed and is looking directly at the camera.

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

Transplant activity overview



Level of recovery

- High
- Medium
- Low

In the **US**, the market with the **strongest recovery YTD**, the number of transplants increased for **all** major organs compared with 2020 and 2019

In **Europe**, recovery is slower and **varies** country by country

Example of level of recovery - lungs

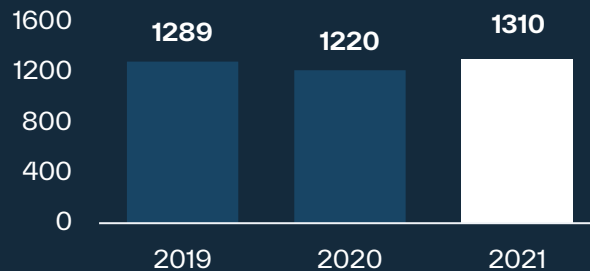
Lung transplants

U.S.

Level of recovery

- No of LTx:
High
- Machine perfusion (EVLP):
Medium/high

Number of transplants (U.S.)



Europe/RoW

Level of Recovery

- No of LTx:
Medium/Low
- Machine perfusion (EVLP):
Low/medium

Commercial initiatives – Q2

General - all markets

- Increased interaction with customers
- Increased number of customer training events
- Webinars held with high attendance
- Preparations for autumn exhibitions (such as ESOT in Milan, IT)

North America

Continued investments in the Commercial organization

- Marketing manager recruited
- Appointment of Abdominal Key account manager
- Increased headcount in sales team

Europe

Continued investments in the Commercial organization

- Global product manager abdominal recruited

Reimbursement

- Several reimbursement initiatives taken (UK, Benelux, France, Germany)

Highlights in Q2

Financial highlights

- Net sales up 116%¹ to SEK 59 million (30)
 - Thoracic up 82 %¹ to SEK 50 million (30)
 - Abdominal up 126 %¹ to SEK 9 million (-)
- Machine perfusion 52% (39) of net sales
- Gross margin non-durable goods 76% (81%)
- EBITDA margin (adjusted)² 14% (-3%)
- SEK 10 million in one-time costs
 - Whereof SEK 3,4 Million related to M&A activities

¹ Local currencies

² EBITDA adjusted with costs associated with a share-based bonus program for employees outside Sweden, integration costs and M&A activities, 10 MSEK in net total.

Significant events

- XVIVO submits 510(k) with FDA for Kidney Assist Transport
- NICE -The National Institute for Health and Care Excellence - gives Support for EVLP in the UK
- New clinics included in the European clinical trials for Heart Preservation and PrimECC.
- XVIVO to start the digital transformation journey together with UMC Groningen

A woman with long brown hair, wearing a grey textured 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 bright, modern office with large windows.

Financial Performance Q2

Net sales and results in Q2

SEK Thousands	Apr-Jun 2021	Apr-Jun 2020	Change	YTD
Net sales	59,263	30,393	95%	117,588
Gross income	44,547	23,102	93%	87,227
Gross margin, %	75	76		74
Operating income	-9,350	-12,709	-26%	-6,167
EBITDA (Operating income before depreciation and amortization)	-1,533	-5,452	-72%	9,674
EBITDA, %	-3	-18		8
EBITDA (adjusted) ¹	8,402	-954	981%	14,670
EBITDA (adjusted) ¹ , %	14	-3		12
Earnings per share ² , SEK	-0.31	-0.60	-48%	-0.10

¹ Adjusted for effect from costs attributable to cash-based incentive program for employees outside Sweden, integration costs as well as costs associated with the M&A activities. Adjusted amount net for the quarter, amounts to SEK 9.9 (-4.5) million for. Adjusted amount net for the period amounted to SEK 5.0 (-2.0) million.

²After dilution

Thoracic – Q2 Highlights

Net Sales

SEK 50 million (30)

Local currency growth

+82 %

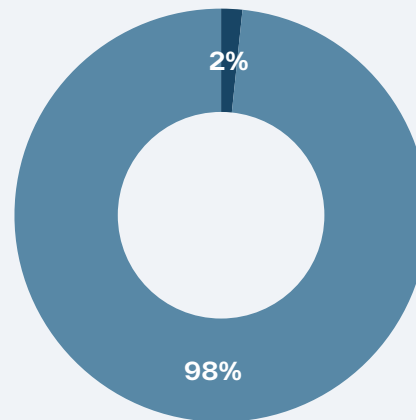
Gross margin

80 % (76)

Gross margin non-durable goods

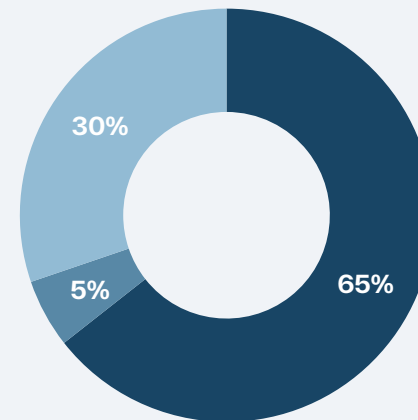
80% (81)

Net sales by segment (Q2)



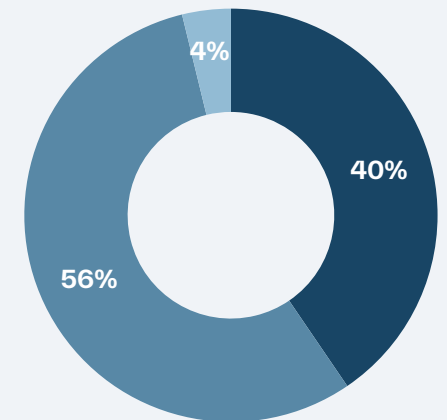
■ Durable goods
■ Non-durable goods

Net sales by region (Q2)



■ Americas
■ APAC
■ EMEA

Net sales by product category (Q2)



■ Machine perfusion
■ Static preservation
■ Other

Abdominal – Q2 Highlights

Net Sales SEK
9 million (-)

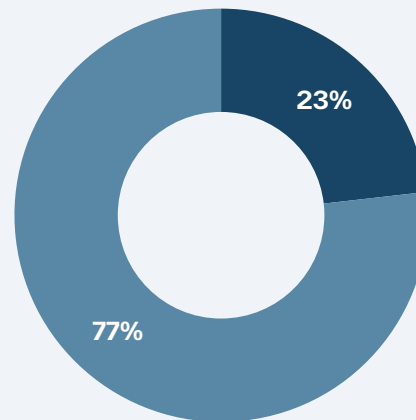
Local currency growth
+126 %

Gross margin
52 % (-)

Non-durable goods
50% (-)

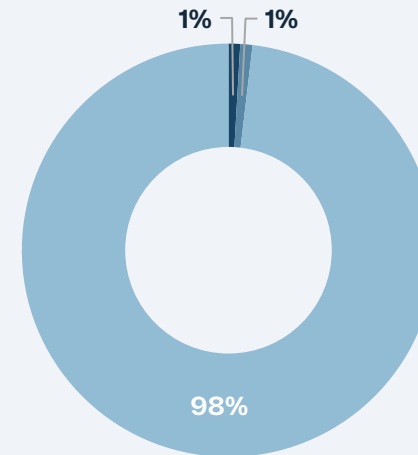
Durable goods
60% (-)

Net sales by segment (Q2)



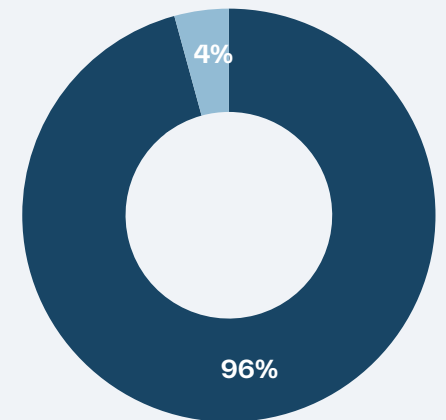
■ Durable goods
■ Non-durable goods

Net sales by region (Q2)



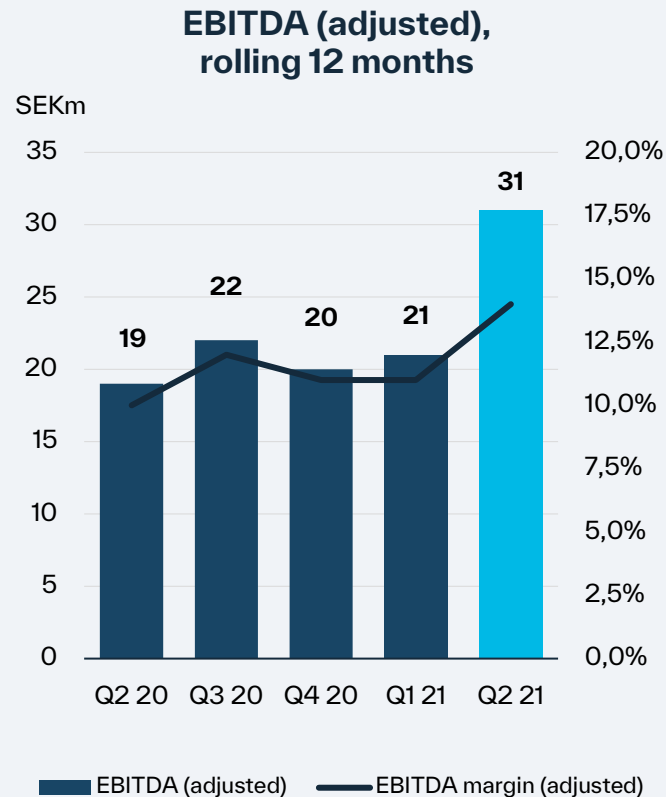
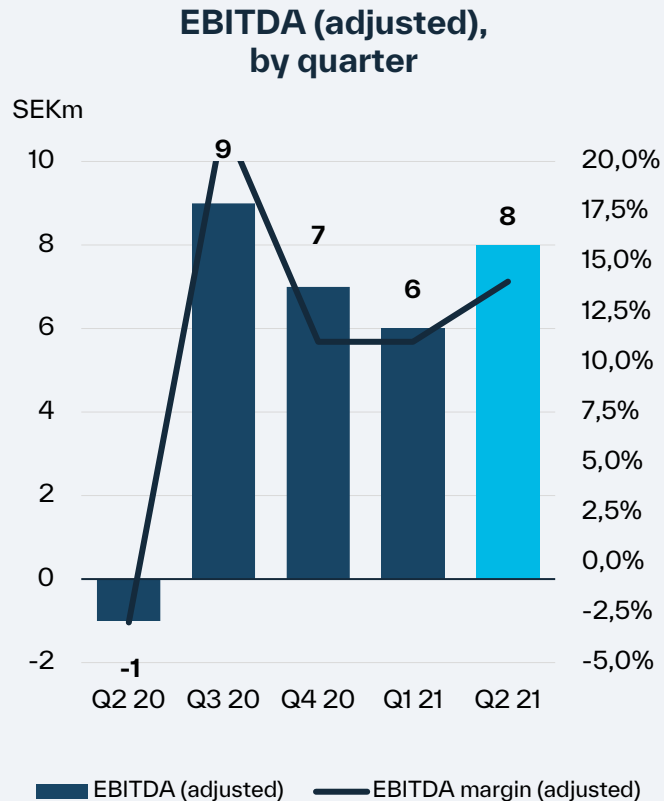
■ Americas
■ APAC
■ EMEA

Net sales by product category (Q2)



■ Machine perfusion
■ Static preservation
■ Other

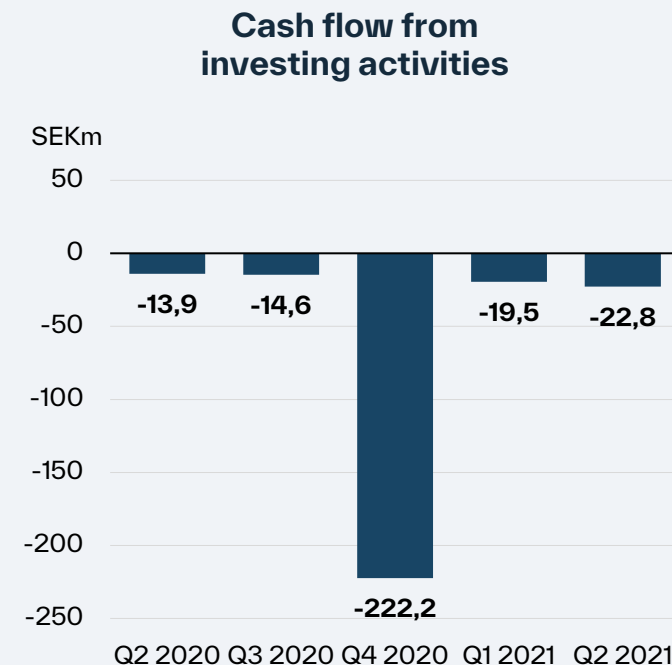
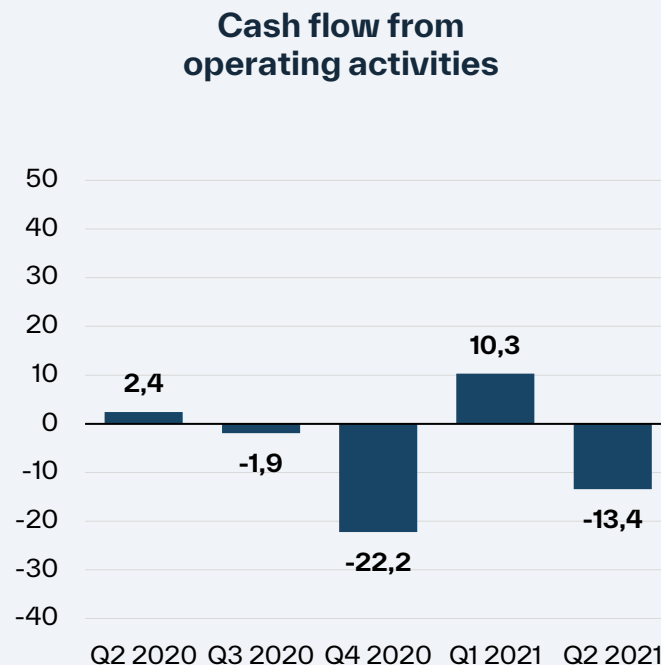
EBITDA



- EBITDA (adj) in Q2 SEK 8 million, 14 % (-3 %)
- Adj. for one-time costs: SEK 10 million
- EBITDA (adj) R12 in Q2 SEK 31 million, 14 % (10 %)

Financial position and cash flow (June 30, 2021)

- Cash flow from operating activities SEK -13 million (2)
- Total Cash flow in Q2 SEK -36 million (-12)
- Cash or cash equivalents SEK 311 million (140) by end Q2
- Net working capital SEK -11 million (3)
- Total long-term liabilities SEK 69 million (5)
- Total assets SEK 1,149 million (620) and equity SEK 1,011 million (570), corresponding to an equity/assets ratio of 88% (92)



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. They appear to be in a casual conversation. The background is out of focus, showing a wooden beam and a white wall.

Significant events

Important milestone within abdominal transplantation

- In May 2021, XVIVO announced its submission of a **510(k)** file with US FDA for **Kidney Assist Transport**
- The goal is to receive market clearance in the US by end Q3
- The Kidney Assist Transport is XVIVO's transportable organ preservation system designed for kidneys
- The submission is an important milestone for XVIVO towards establishing a commercial presence within abdominal transplantation in the US

Q3 Focus areas

- Finalize US go to market strategy
- Initiate customer pre-launch activities
- Training and education
- Secure optimized manufacturing and supply chain

Target: US launch in the beginning of Q4 2021



NICE gives support for EVLP (UK)

In May, XVIVO announced that The National Institute for Health and Care Excellence (NICE), has issued interventional procedure guidance recommending the use of Ex Vivo Lung Perfusion (EVLP) for preservation of lungs

Completed in Q2

- Guidelines published on Website (May)
- Perfadex Plus UK tender awarded (June)

Next steps

- XVIVO has initiated a process for reimbursement based on NICE guidelines
- Collation of clinical evidence on EVLP in UK
- Business case to be submitted to NHSBT
- Estimated reimbursement Q1 2023

Aug 2021



Regional EVLP commences

Jan 2022



EVLPs completed

Sept 2022



Collation of Clinical Data Preparation & Submission of Business Case

Q1 2023



Estimated Reimbursement Outcome

Progress in clinical trials

European Heart preservation trial

5 centers are currently including patients:

- Sahlgrenska University Hospital (Gothenburg, SE)
- University Hospitals Leuven (Leuven, BE)
- Hospital Puerto de Hierro (Madrid, ES)
- La Pitié Salpêtrière (Paris, FR)
- *One not published (DE)*

Next up: German, Austrian and an Italian centre

In Q2, 4 new, prominent centers showed interest in the trial. For these centers, the application process has started.

Timeline: Last patient in Q4 2022
/ Commercial launch Q1 2024

PrimECC

1 site is currently including patients, Sahlgrenska Hospital, SE

- Ethics committee applications submitted to Rikshospitalet in Oslo, NO and Rigshospitalet in Copenhagen, DK.
- Discussions have also been initiated with two German high volume centers.

Timeline: Clinical data submission (MDR) in Q2 2023

XVIVO to start its digital transformation journey

- XVIVO and University Medical Center Groningen (UMCG) will carry out a pilot-project in advanced analytics
- The project, named XCEPT, aims to extract liver perfusion data from XVIVO's machine for liver perfusion, Liver Assist
- Will enable advanced analysis prior to transplantation
- The analysis will help surgeons to make more data-driven decisions and increase the number of successful liver transplants
- To be launched together with the Liver Assist in the future, if successful





Outlook 2021

Outlook 2021

Strategic Objectives for Q3-Q4

- Launch 2022-2026 strategic plan
- Launch Kidney Assist Transport in the US
- FDA submission for Liver Assist
- Speeding up the Heart Preservation and PrimECC clinical trials
- Increase reimbursement focus in Europe



XVIVO Capital Markets Day September 23

Save the date!

Location: GoCo Health Innovation City (Gothenburg)
and online webcast

Agenda: Market and trends, strategy and financials,
deep dives in our Thoracic and Abdominal business
areas, KOL interviews and Q&A

**Invitation will be distributed in August
through press release**

Our vision

Nobody should
die waiting for
a new organ
