

XVIVO

# Årsstämma 2026

Göteborg, 27 april 2026



**Kim Castellano**  
Heart transplant recipient, US

# Anförande av verkställande direktören



**Christoffer  
Rosenblad**  
CEO

XVIVO

# 2025 Highlights



**Alex Moroianu**  
Heart transplant recipient, AU

XVIVO

# 2025 Financials – at a glance

Net Sales

**SEK 812 Million**

Sales growth

**Organic growth +3%\***

- Acquired growth +1%
- Currency effect -5%
- Total growth -1%

EBITDA

**20% (21)**



## Thoracic

**Net Sales**

SEK 509 million

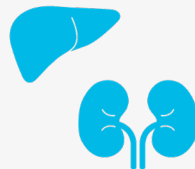
**Gross margin**

85%

Organic growth,  
local currencies

Net sales

**-2%\*\***



## Abdominal

**Net Sales**

SEK 225 million

**Gross margin**

61%

Net sales

**+30%**



## Services

**Net Sales**

SEK 78 million

**Gross margin**

33%

Net Sales

**-5%**

\*Total organic growth adjusted for trial revenue was +8 %

\*\*Thoracic organic growth adjusted for trial revenue was +4%

# Significant events in 2025

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1

**XVIVO enabled 13,000** life-saving transplants

2

**12-month data** from the European multicenter heart preservation trial presented at ISHLT

3

**Delay in CE approval** for XVIVO's perfusion solution for heart preservation

4

**European DCD heart trial 'HOPE at Heart'** with direct procurement – recruitment completed

5

First patient enrolled in the **US PRESERVE CAP study** for XVIVO Heart Assist Transport

6

**40% of all DBD hearts** in Australia

7

**First-of-its-kind EVLP OPO-model** launched through a perfusion partnership

8

**Liver Assist™ reaches 25%** penetration in core EU markets

9

**Global launch of XVIVO Insights™** for Kidney Assist Transport™ and Liver Assist™

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# Q1 2026 highlights



**Kim Castellano**  
Heart transplant recipient, US

# Q1 Financials – at a glance

Net Sales

**SEK 241 Million**

Sales growth

**Organic growth +23%\***

- Currency effect -13%
- Total growth 10%

EBITDA

**21% (20)**



## Thoracic

**Net Sales**

SEK 160 million

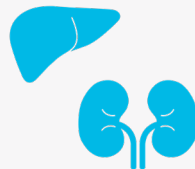
**Gross margin**

83%

Organic growth,  
local currencies

Net sales

**+27%\*\***



## Abdominal

**Net Sales**

SEK 66 million

**Gross margin**

54%

Net sales

**+24%**



## Services

**Net Sales**

SEK 16 million

**Gross margin**

18%

Net Sales

**-10%**

\*Total organic growth adjusted for trial revenue was +18%

\*\*Thoracic organic growth adjusted for trial revenue was +19%

# Q1 Operations - Highlights

1

Back-to-back **record sales** quarter

2

Proof-of-concept from 1st **OPO EVLP hub** model

3

**Kidney sales** acceleration - growing interest in NAM

4

Last patient included in **CAP** - rapid enrollment

5

**Record penetration for heart** in Australia - DBD 52% and first DCD performed

6

Compassionate use **heart sales** in **4 EU countries**

7

**Flowhawk** used by 6 of 10 largest US tx programs

8

First 5 **NRP** Organ recovery contracts signed



# ISHLT 2026

*XVIVO highlights at the on-going ISHLT in Toronto April 22-25:*

## Late breaking abstracts

- **Preliminary 12-month data from the US PRESERVE trial** presented by Dr. Victor Pretorius
- **HOPE in direct procurement DCD – first clinical trial** presented by Prof. Filip Rega

## Industry symposia

- *April 22: From NRP to EVLP: Multimodal strategies to expand lung utilization and improve outcomes*
- *April 24: New HOPE for all hearts: Clinical evidence for HOPE across DBD, DCD, ECD and pediatric transplantation*





# US PRESERVE trial

*Preliminary one-year follow-up data from the US PRESERVE trial for XVIVO's heart technology presented at ISHLT*

- A total of 141 transplant recipients were enrolled at 14 US transplant centers.
- The trial (NCT05881278) included adult recipients of hearts from donors meeting specific risk criteria:
  - estimated cold ischemic time  $\geq 4$  hours,
  - or  $\geq 2$  hours with one or more extended-criteria risk factors (such as donor age  $\geq 50$ , down-time  $\geq 20$  mins, hypertrophy/septal thickness  $>12$ -  $\leq 16$ mm,
  - or angiographic luminal irregularities with no significant CAD),
  - or donation after circulatory death (DCD) donors.

## *The preliminary data*

- ✓ **The trial met its pre-specified primary and secondary endpoints**
- ✓ **The primary efficacy endpoint** of overall success rate at 30 days (defined as absence of severe primary graft dysfunction (PGD), death, re-transplant, or mechanical support at Day 30) was **92.1%**
- ✓ **The primary safety endpoint** of patient survival at day 365 was **91.4%**
- ✓ **Secondary endpoint** analysis demonstrated an incidence of severe PGD at 24 hours of **7.9%**

CAUTION—Investigational device. Limited by Federal (United States) law to investigational use. The safety and effectiveness of this device have not been established in the US.



# HOPE-at-Heart trial

*Encouraging results from first clinical trial using hypothermic oxygenated perfusion (HOPE) in direct procurement DCD heart transplantation presented at ISHLT*

- In a single-arm, proof-of-concept trial 40 adult heart transplant recipients across four European transplant centers in Belgium and the Netherlands were enrolled.

*“These results are highly encouraging. For the first time, we have prospective clinical evidence supporting the feasibility of direct procurement combined with HOPE in DCD donor hearts, with strong early outcomes and a low rate of severe primary graft dysfunction.”*

*- Prof. Filip Rega, Coordinating Trial Investigator*

## The results

- ✓ **The trial met its pre-specified primary and secondary endpoints**
- ✓ The primary endpoint, patient survival at 30 days, was 98 %
- ✓ Secondary endpoints demonstrated a 5 % incidence of severe primary graft dysfunction (PGD) at 24 hours and a 10 % incidence of post-operative mechanical circulatory support the first 30 days.
- ✓ The mean total preservation time was **over 300 minutes**.
- ✓ **No hearts were discarded** due to device malfunction or any device-related issue.

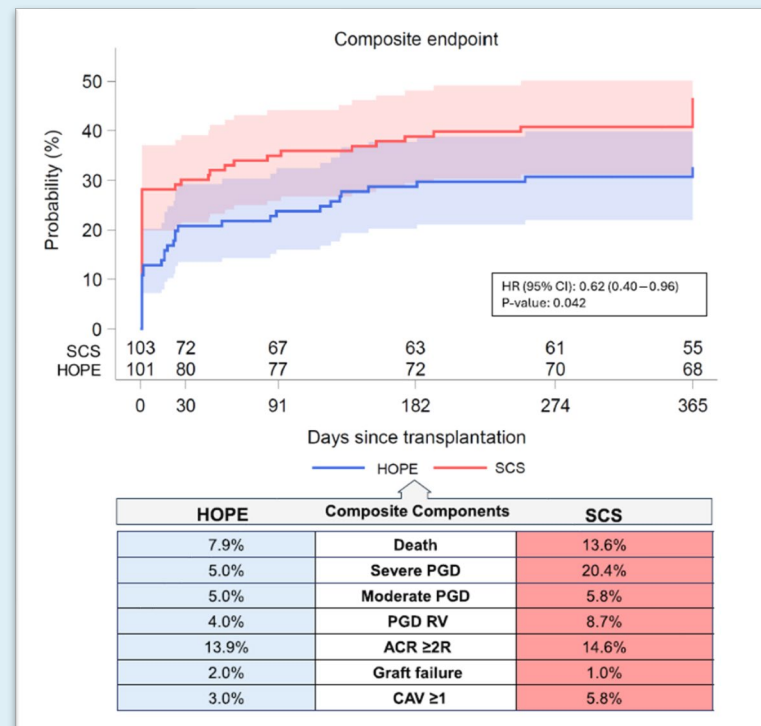
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# New publication on NIHP2019

The European multicenter heart trial, NIHP2019, results have now been published in the European Heart Journal<sup>1</sup>.

## Recap on the results:

- **76 % risk reduction in severe PGD** – the leading cause of mortality after heart transplantation
- The risk reduction translated into an improved survival in the XVIVO Group with **92 percent survival** vs 86 in the control arm
- Corresponding to **additionally 6 out of 100 lives saved** after usage of XVIVO Heart Assist Transport



## Hypothermic oxygenated perfusion versus standard treatment of donor hearts in heart transplantation: extended follow-up of the NIHP2019 trial

Filip Rega<sup>1,\*</sup>, Guillaume Lebreton<sup>2</sup>, Marylou Parquet<sup>3</sup>, Sebastian Michel<sup>4,5</sup>,  
Andriessche<sup>1</sup>, Udo Boeken<sup>6</sup>, Alberto Forteza<sup>7</sup>, Pradeep Kaul<sup>8</sup>,  
Man F. Gummert<sup>6</sup>, Christoph Knosalla<sup>15,16</sup>,  
Half of the NIHP2019 investigators

Cardiac Surgery Department, Pitié-Salpêtrière Hospital, APHP, Paris, France; <sup>2</sup>Heart Research, Université Paris Cité, Paris, France; <sup>3</sup>Clinic of Cardiac Surgery, Research, Munich Heart Alliance, Munich, Germany; <sup>4</sup>Clinic of Cardiac Surgery, Bochum, Bad Oeynhausen, Germany; <sup>5</sup>Department of Cardiac Surgery, Royal Papworth Hospital NHS Foundation Trust, Cambridge, UK; <sup>6</sup>Department of Cardiac Surgery, Birmingham NHS Trust, Birmingham, UK; <sup>7</sup>Department of Cardiac Surgery, Puerta de Hierro Majadahonda Hospital, Madrid, Spain; <sup>8</sup>Department of Cardiac Surgery, Deutsches Herzzentrum der Charité, Berlin, Germany; <sup>9</sup>Department of Cardiac Surgery, University Hospital Leuven, Leuven, Belgium; <sup>10</sup>Department of Cardiac Surgery, University Hospital Leuven, Leuven, Belgium; <sup>11</sup>Department of Cardiac Surgery, University Hospital Leuven, Leuven, Belgium; <sup>12</sup>Department of Cardiac Surgery, University Hospital Leuven, Leuven, Belgium; <sup>13</sup>Department of Cardiac Surgery, University Hospital Leuven, Leuven, Belgium; <sup>14</sup>Department of Cardiac Surgery, University Hospital Leuven, Leuven, Belgium; <sup>15</sup>Department of Cardiac Surgery, University Hospital Leuven, Leuven, Belgium; <sup>16</sup>Department of Cardiac Surgery, University Hospital Leuven, Leuven, Belgium.

...into sustained improvements in outcome and patient safety. ...and methods have been previously described.<sup>1-4</sup> NIHP2019 (NCT03991923) is an open-label, randomized controlled trial conducted in 15 centres across 8 European countries. Adult candidates were transplanted with either heart preserved with either ischaemic SCS or with a portable machine perfusion system (XVIVO Heart Assist Transport, Leuven, Sweden). Transplant procedures and postoperative care were performed in accordance with the current best practices of the respective centre. The current study reports on the predefined, key secondary endpoint of the trial: the occurrence of a composite endpoint occurring within 12 months post-transplant and including: any cause of death, primary graft dysfunction (PGD) (moderate, severe, and right

<sup>1</sup>https://academic.oup.com/eurheartj/advance-article/doi/10.1093/eurheartj/ehag264/8654637



# Regulatory update

# Clinical Trial Status & Tentative Timeline



Organ	Region	Key Details	PRECLINICAL	CLINICAL	REVIEW & FOLLOW-UP	MARKET APPROVAL
HEART	Europe	<ul style="list-style-type: none"> <li>Patient enrolment completed May 2023</li> <li>204 patients included across 15 centers across 8 countries</li> <li>Results were published in The Lancet in August 2024</li> </ul>			12-month patient follow-up completed	Commercial launch pending CE-mark*
HEART	Australia	<ul style="list-style-type: none"> <li>Trial included 36 patients from 5 centers</li> <li>Last patient included in December 2022</li> <li>Results published in <i>The Journal of Heart &amp; Lung Transplantation</i> in November 2023</li> </ul>			12-month patient follow-up completed	Commercial launch pending CE-mark. Currently sold under <i>Special access scheme</i>
HEART	USA	<ul style="list-style-type: none"> <li>PRESERVE trial included 141 patients across 14 US transplant centers</li> <li>Last patient included in November '24</li> <li>Prel. results presented at ISHLT in April '26</li> </ul>		13-month patient enrollment	12-month patient follow-up completed Submission prep.	Submission and PMA approval process
LIVER	USA	<ul style="list-style-type: none"> <li>FDA Breakthrough Device Designation</li> <li>IDE application for DeLIVER trial approved in February 2025</li> <li>Multicenter trial including 215 patients across up to 20 centers</li> </ul>		No patient enrolled. Trial activities temporarily paused to evaluate alternative regulatory pathways		

\*Pending regulatory approval



# Update - Liver Assist™ in the US

## *Regulatory pathway update*

- All regulatory **approvals obtained** to initiate the **PMA study**
- Trial activities temporarily paused to evaluate **faster and more cost-efficient** regulatory pathways
- First **HOPE DeNovo** liver perfusion now **FDA-approved**
- Planning for a Q-sub meeting with FDA during Q2 to **define regulatory path forward**



# Outlook

Alex Moroianu  
Heart transplant recipient, AU

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# XVIVO is changing the future of organ transplantation

## Focus 2026


- Drive continued **EVLP adoption** in the US by leveraging **centralized perfusion service models**
- Strengthen our commercial presence related to **Flowhawk** and **Organ recovery** in the US
- Further develop our **European leadership** in liver perfusion
- **Obtaining CE-mark** and start commercialization of **XVIVO Heart Assist Transport**-technology in Europe, and also the submission of the regulatory file to the **FDA**
- Decide on regulatory pathway for **Liver Assist in the US**
- **Continued investments in US** commercial organization to support product and service expansion and prepare heart commercialization



# 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 and service models** have proven to increase the number of organs used for transplantation
- **XVIVO** has unique, innovative and world leading products on the market or in R&D pipeline



A woman with reddish-brown hair, wearing a grey sweater and a dark patterned scarf, sits on a stone wall. She is looking off to the side with a thoughtful expression. The background shows a landscape with trees and a cloudy sky.

# Nobody should die waiting for a new organ

**Fredrica Höglund**  
Liver transplant recipient, Sweden