

XVIVO

XVIVO Capital Markets Day

September 21, 2022



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Agenda

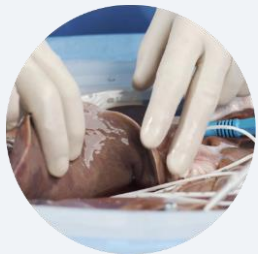
14:00 - 14:20	Strategy & financials	<i>Dag Andersson - CEO Kristoffer Nordström - CFO</i>
14:20 - 14:40	Machine perfusion strategy	<i>Johan Holmström - CCO</i>
14:40 - 15:00	Beyond Product: STAR Teams and Avionord M&P	<i>Christoffer Rosenblad - Global Bus. Dev. & Service Dir.</i>
15:00 - 15:15	Regulatory Strategy	<i>Katrin Gisselfält - Global QA/RA Director</i>
15:15 - 15:45	XVIVO Heart technology: The power of oxygenation and the clinical trials	<i>Andreas Wallinder - CMO Jaya Tiwari - VP Clinical & RA USA Guest Speaker - Prof. David McGiffen (Alfred Health, Melbourne, Australia)</i>
15:45 - 16:00	Capital Markets Day Summary and Q&A	

This is XVIVO

Business area



Thoracic



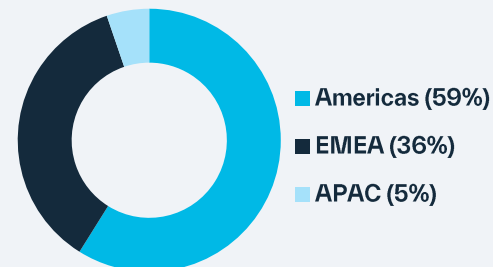
Abdominal



Services



Main markets 2022



Founded
1998

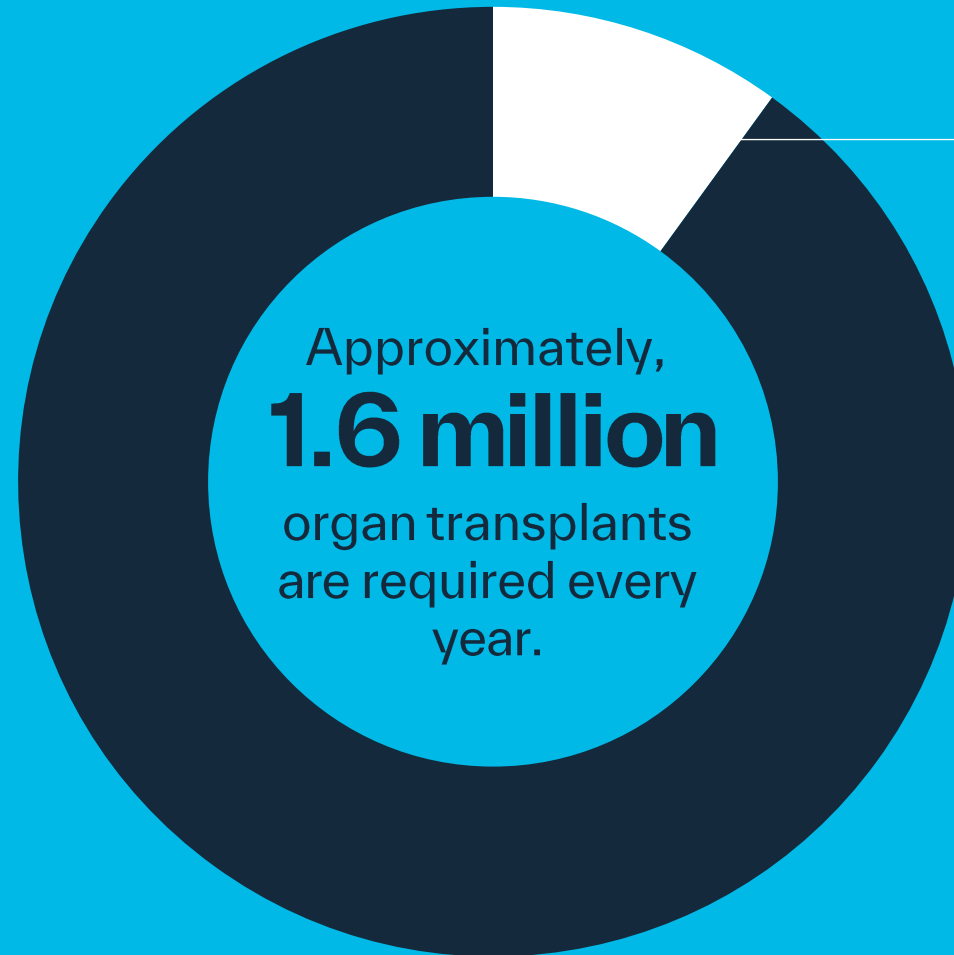
Employees
~120

HQ in Gothenburg
Sweden

The share is listed on
NASDAQ
Stockholm mid-cap

The challenge

The need



With only

160,000

organ transplants performed globally each year, this only covers

10% of the total need.

Organ utilization rates

Global Average (2015-2021)



Limiting factors



Organ quality

Clinicians lack the confidence to use marginal organs



Capacity

Transplant clinics have limited resources to recover, preserve, and perfuse organs



Logistics

Limitations on 'out-of-body time' create constraints on allocation and distribution opportunities

Our offer: We enable safe use of more organs



We increase the availability of organs



We improve organ preservation



We improve organ function and survival

A woman with short, light brown hair is leaning against the thick, textured trunk of a tree. She is wearing a light grey crew-neck sweater over a white collared shirt. She has a neutral expression and is looking slightly to the right of the camera. The background shows a paved road and a stone wall under a cloudy sky.

We believe in an extended life of organs

Nobody should
die waiting for
a new organ

Market trends

Market trends in transplantation



Machine Perfusion



Political Ambitions –
Policy & reimbursement



Services



Digitalisation



Xenotransplantation



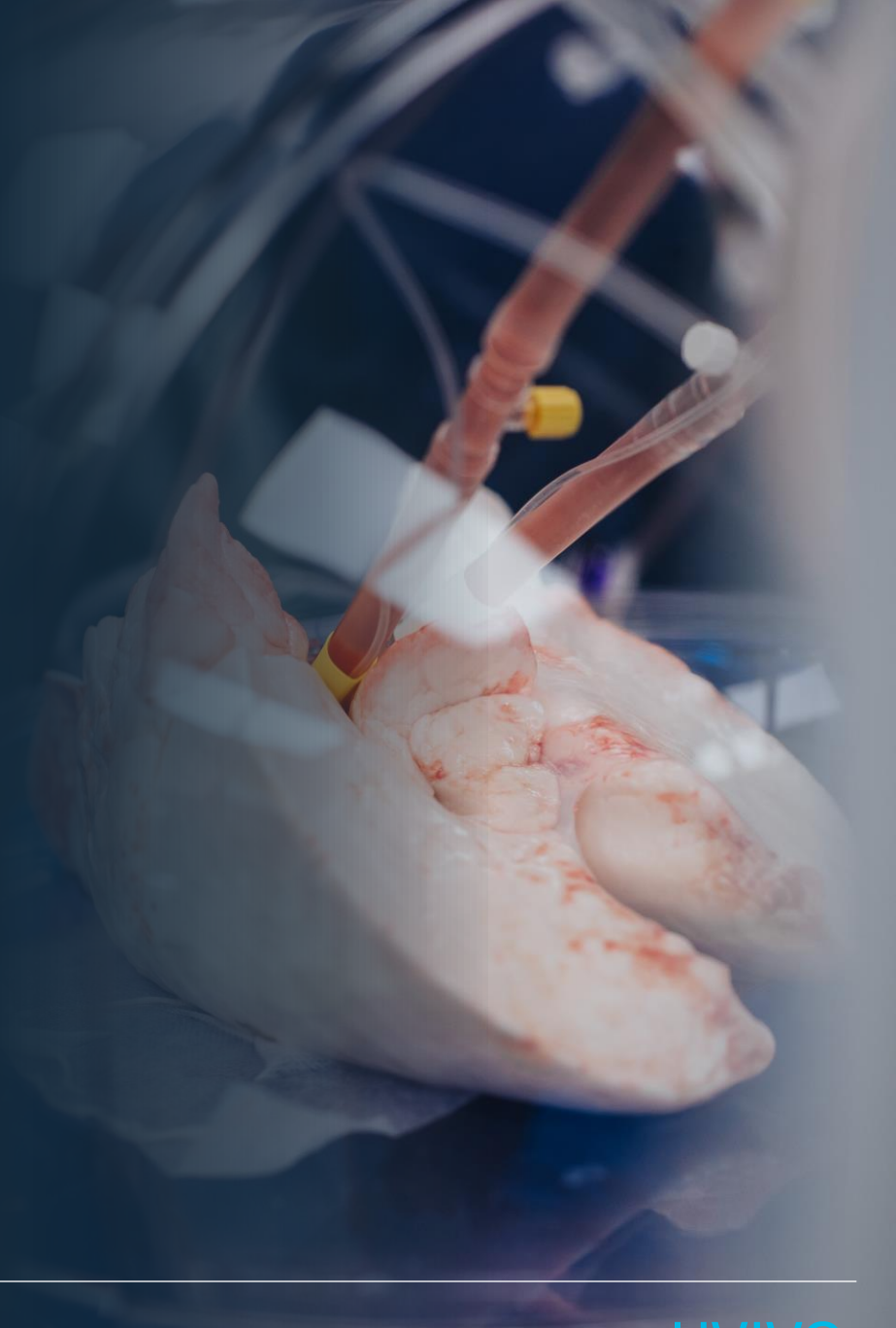
Strategy

Achievements last 12 months

- ✓ Abdominal launch USA – with Kidney Assist Transport FDA 510(k) clearance
- ✓ Strong double digit growth
- ✓ Continued investment in clinical, R&D, and commercial organisation
- ✓ Significant progress in heart trials – Europe & Australia/ New Zealand
- ✓ Completion of 2 acquisitions: STAR Teams and Avionord M&P



Sharpened strategic objectives



Organisation – Extended Management Team



Dag Andersson
CEO



Katrin
Gisselfält

Global QA/RA Dir.



Charlotte
Walldal

Global R&D Dir.



Christoffer
Rosenblad

Global Bus. Dev &
Service Dir.

Hassan Tetteh
Managing Director
STAR Teams



Kristoffer
Nordström

CFO



Jaya
Tiwari

VP Clinical &
Regulatory Affairs
US



Andreas
Wallinder

CMO

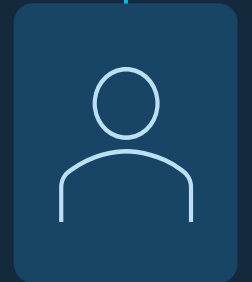


Johan
Holmström

CCO

Rob Baumann
Sales Director
North America

Estelle Peslerbe
Sales Director
Europe



Vacant

COO

XVIVO as an investment

1

Strengthen leadership position in a rapidly growing market

2

XVIVO's product & service offer increases utilization and availability of organs

3

High margin products create foundation for continued profitable growth

4

Unique R&D portfolio with products ready to launch in a near future

Financials

Kristoffer Nordström,
Chief Financial Officer

Profitable growth - The XVIVO way

**Growing
market**

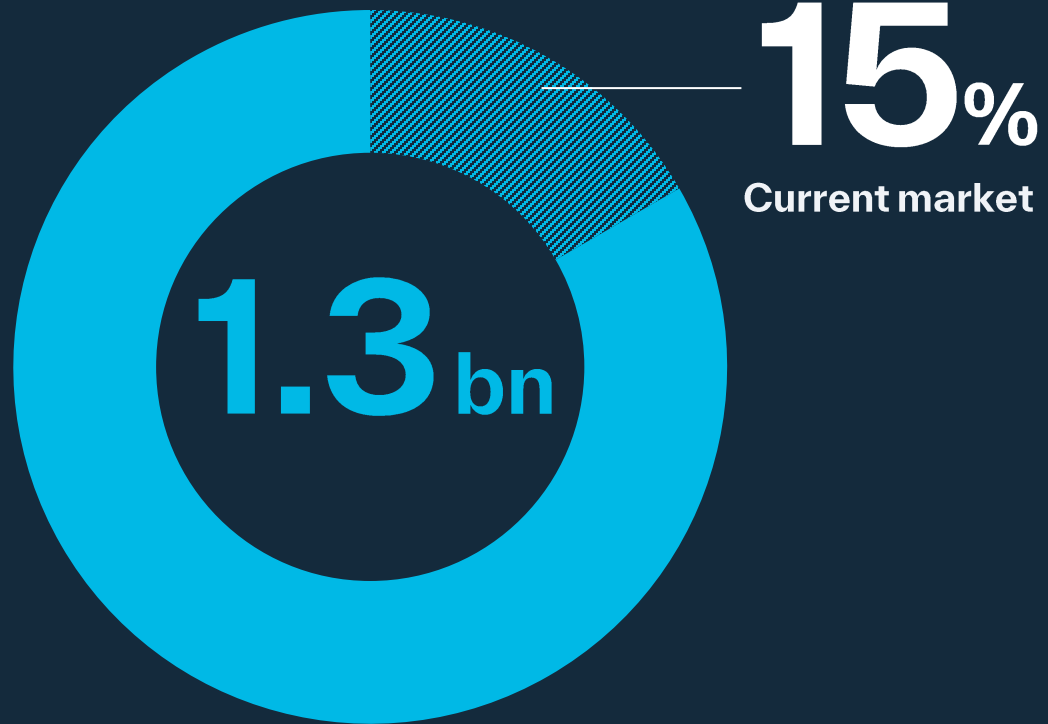
**Clear
growth
drivers**

Profitable

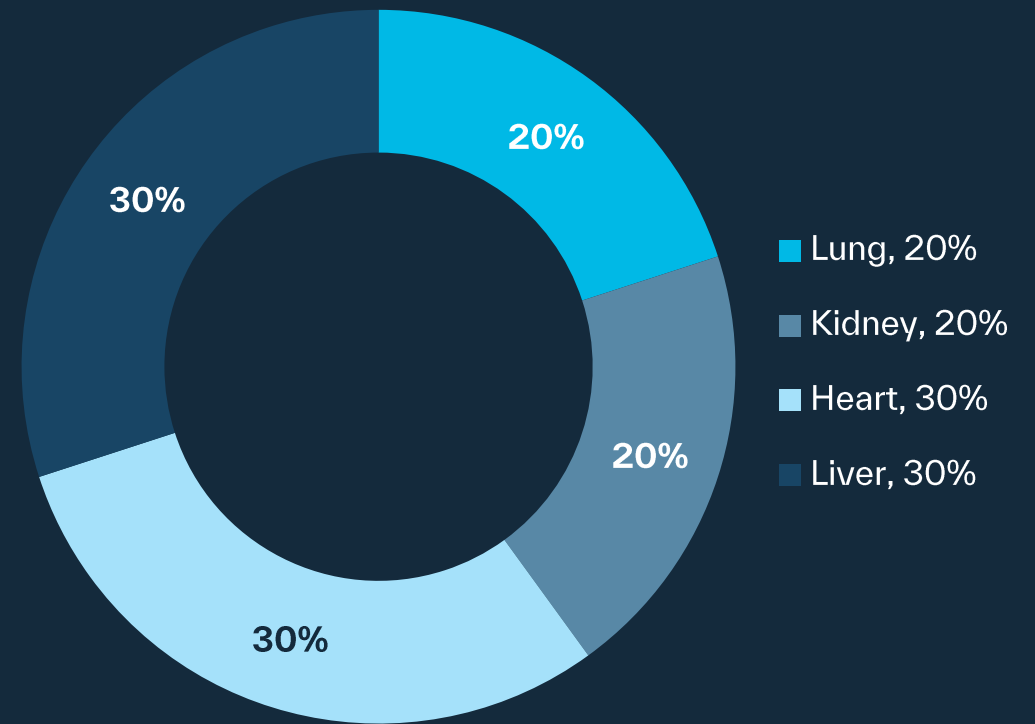
**Well
capitalized**

Market value - Machine perfusion

Total market value potential of machine perfusion*
(USD)



Market potential value split

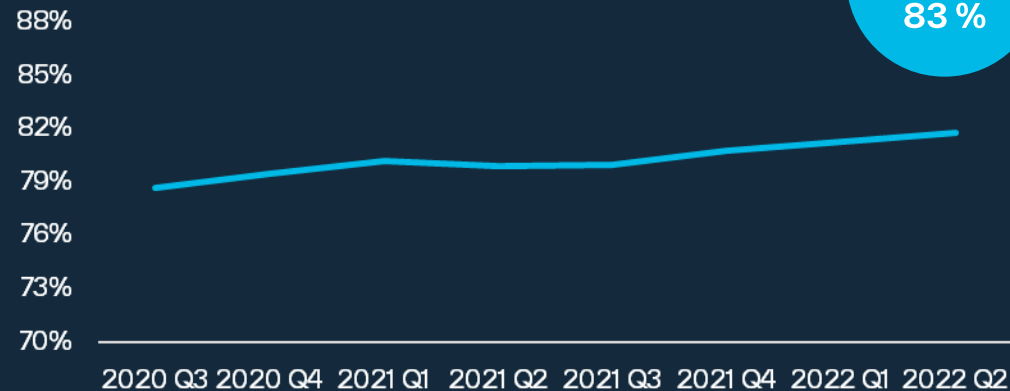


*Deceased donors. Solutions and disposables only (no machines or static preservation)

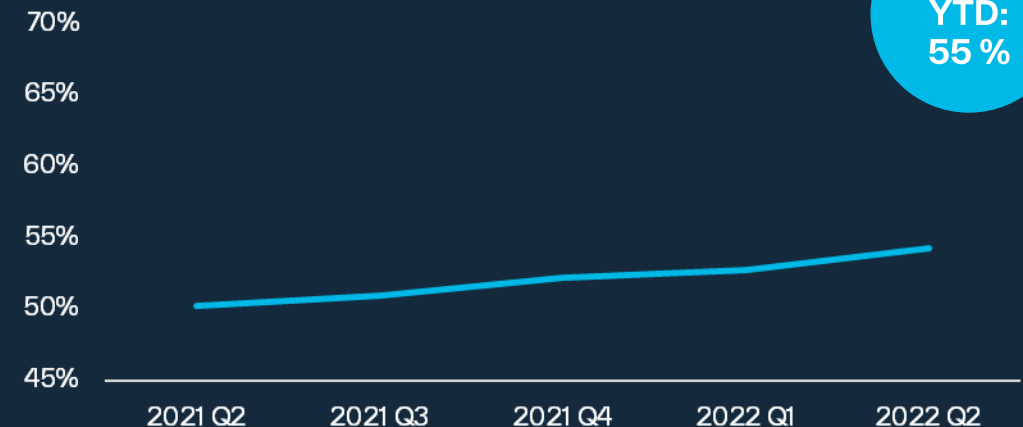
Premium margins driven by differentiation

Recent development

Gross margin thoracic disposables R12M



Gross margin abdominal disposables R12M



Boosters

Kidney Assist Transport US penetration

Avionord integration

Continued price increases

Reimbursement initiatives

Abdominal target 2027 **>70%**

2027 profitability targets

EBIT (%)

≥20

EBITDA (%)

≥30

Capital structure & R&D funding

Expectations 2023-2027

Continued solid and sustainable capital structure

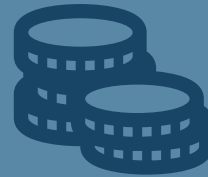
Self-funded commercial expansion

Self-funded R&D pipeline

Key take-aways

5 strategic objectives
which strengthen core
business and drive
expansion of new
products & markets

History of profitability
and continued high
margin business



Operating cash flow will
fund R&D pipeline



Machine Perfusion Strategy

Johan Holmström,
Chief Commercial Officer

Machine perfusion strategy

Background:

Our technologies and solutions for both the thoracic and abdominal organs help make more organs available for transplantation.

Economic Engine:

*Machine perfusion drives our economic engine:
Revenue per Machine*

Our strategic objectives

Market leader abdominal

Change the paradigm of heart preservation

Preferred partner in the transplant process

Accelerate market leadership lungs

New market expansion

Rapid growth of installed machine base



2019

Installed base

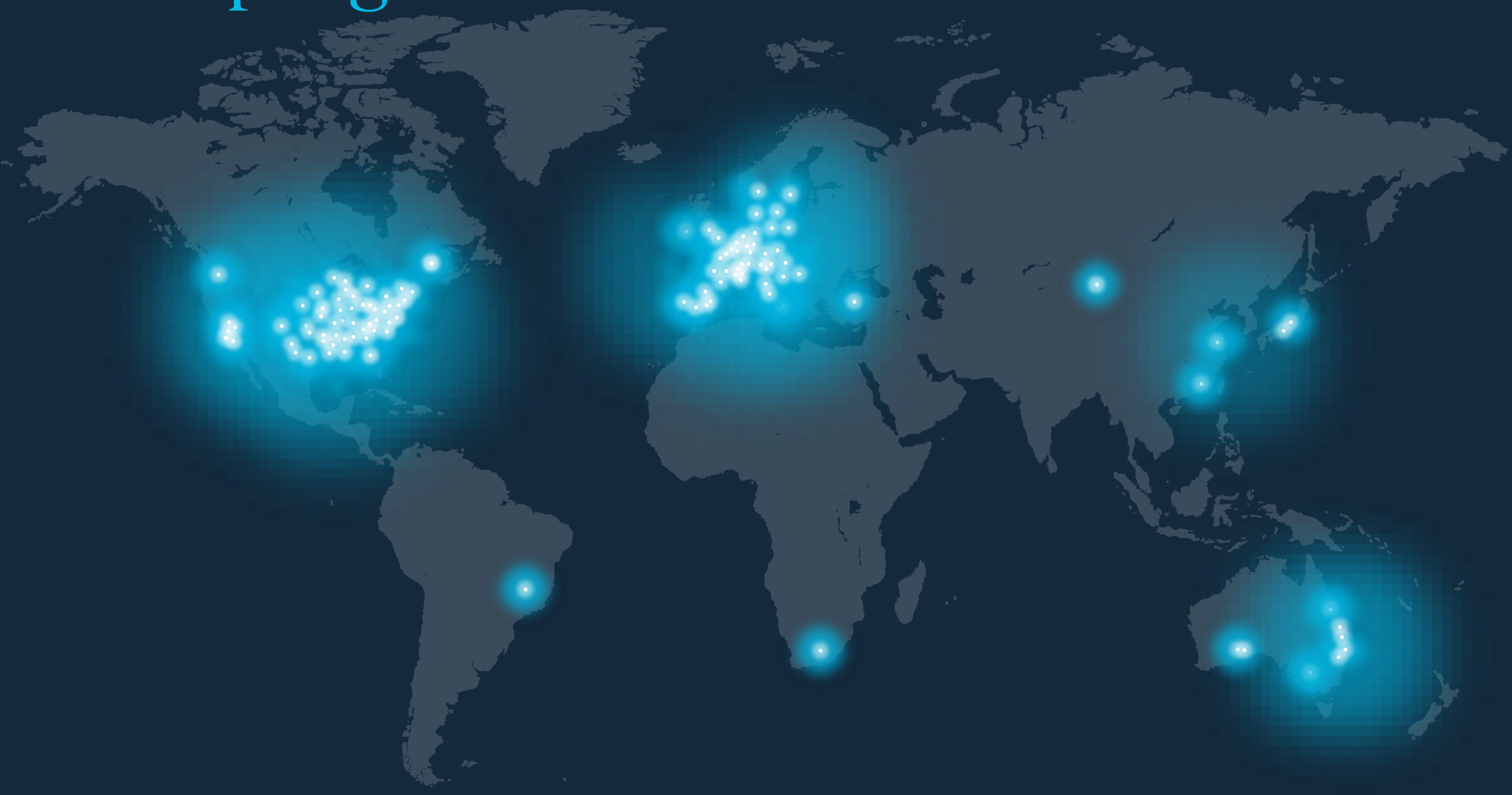


45



98

Rapid growth of installed machine base



Today

Installed base



60

+35%

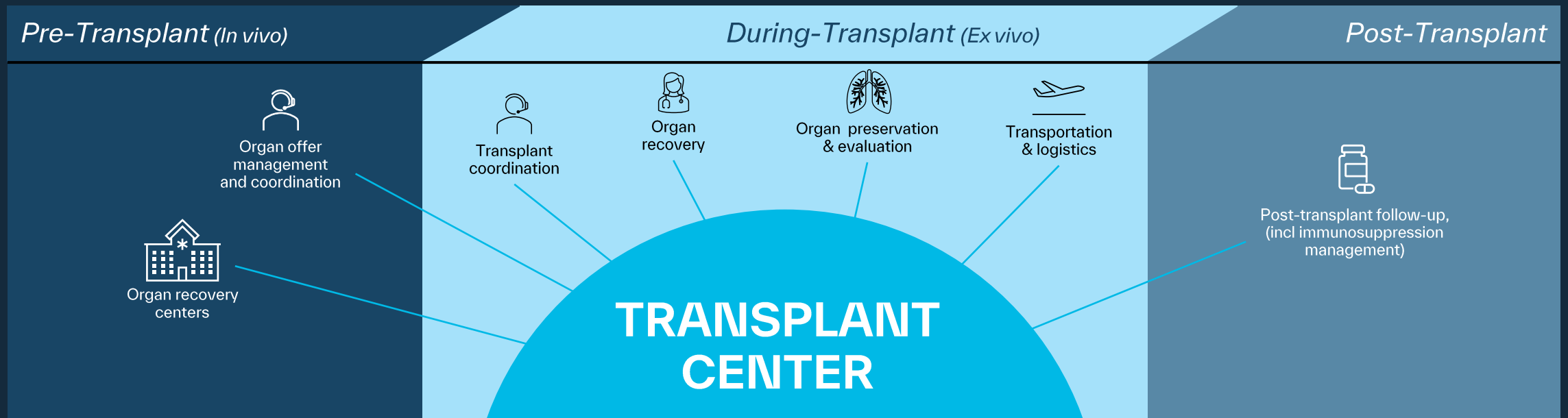


154

+60%

Organ transplantation is a complex and highly specialized resource intense process

Challenge: transplant clinics have constrained resources to recover, preserve, and evaluate organs



Different service offerings are now surfacing in the transplantation market

Key initiatives to increase penetration

Increase revenue per machine

Accelerate installed base of abdominal



- ✓ Commercial excellence with focus on clinical expertise and education
- ✓ Drive organ hub models for accelerated EVLP growth
- ✓ Reimbursement and pricing models customising our value proposition
- ✓ Invest in service models to increase value and customer utilisation

>2 times installed machine base by 2027
>20% penetration of EVLP by 2027

Growth from new product initiatives



Kidney Assist Transport
Full launch in US and EU



XVIVO Heart Technology
EU/ANZ launch Q1 2024
Pre-Market Approval in the US



Liver Assist
Pre-Market Approval in the US



XPS
Launch of next generation

New market expansion

Background:

The fast growing transplant markets in South America and Asia are important growth drivers in XVIVO's journey to becoming a global all organ company

Focus markets:

- ✓ *South America – focus on Brazil*
- ✓ *Select Asian Markets – incl. China*
- ✓ *Middle East & Africa*

Our strategic objectives

Market leader abdominal

Change the paradigm of heart preservation

Preferred partner in the transplant process

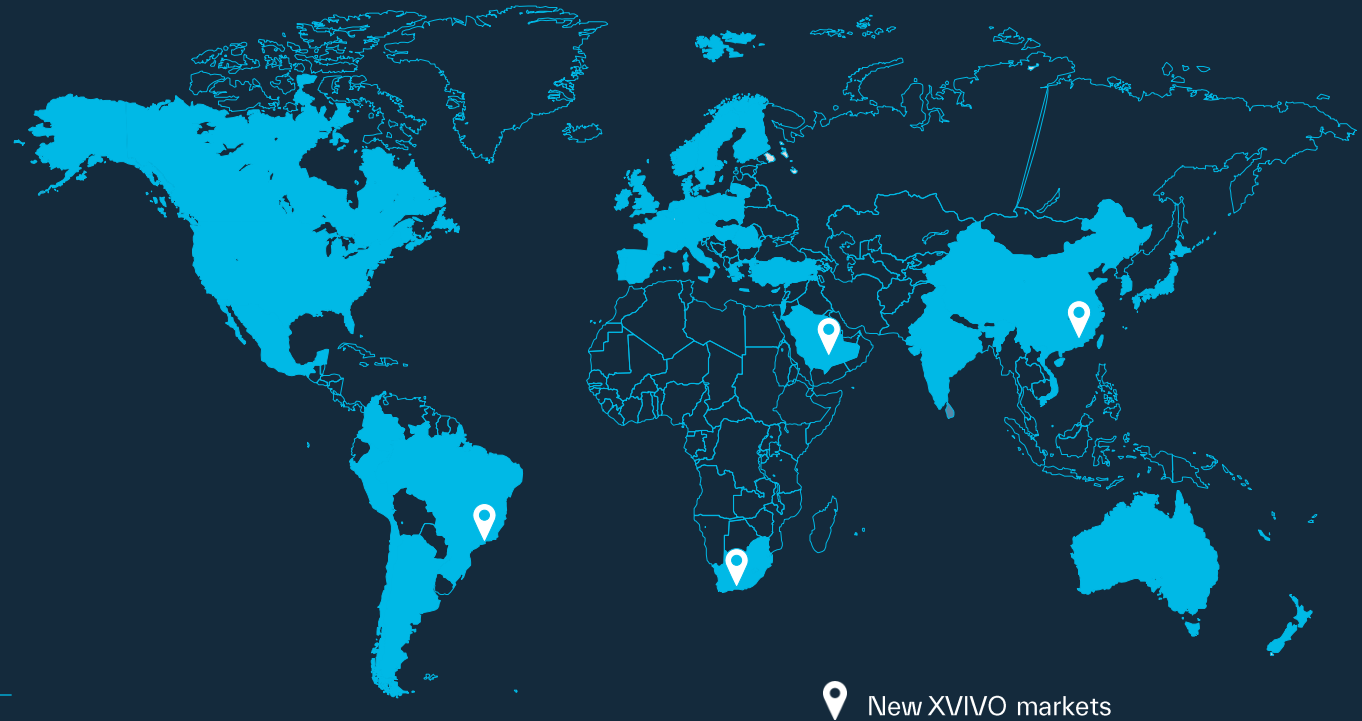
Accelerate market leadership lungs

New market expansion

Accelerated growth from new markets

- Geographic expansion as a **key growth driver**
- Expansion outside our core markets - North America and Europe
- **Controlled** expansion and sustainable build in China
- Increase our focus on Brazil, MEA and select Asian markets
- Product registrations of **full portfolio** – Abdominal and Thoracic

15% of global sales from new markets in 2027



Key take-aways

Rapid growth and increased penetration of machine perfusion in core markets



New product initiatives and commercialization of services to drive growth



15% of global sales from new markets in 2027



Beyond product: STAR Teams and Avionord M&P

Christoffer Rosenblad,
Global Business Development and Service Director

Preferred partner in the transplant process

Background:

- *XVIVO strives to remove hurdles for transplant teams through the transplant process – driving clinical practice by being a thought leader*
- *Identified key hurdles – capacity & logistics:*
 - *Process and resources for recovery of organs*
 - *Resources and scale for machine perfusion*

Definition:

- ✓ *Becoming the preferred partner is about increasing clinician satisfaction by removing hurdles and addressing inefficiencies in the transplant process*

Our strategic objectives

Market leader abdominal

Change the paradigm of heart preservation

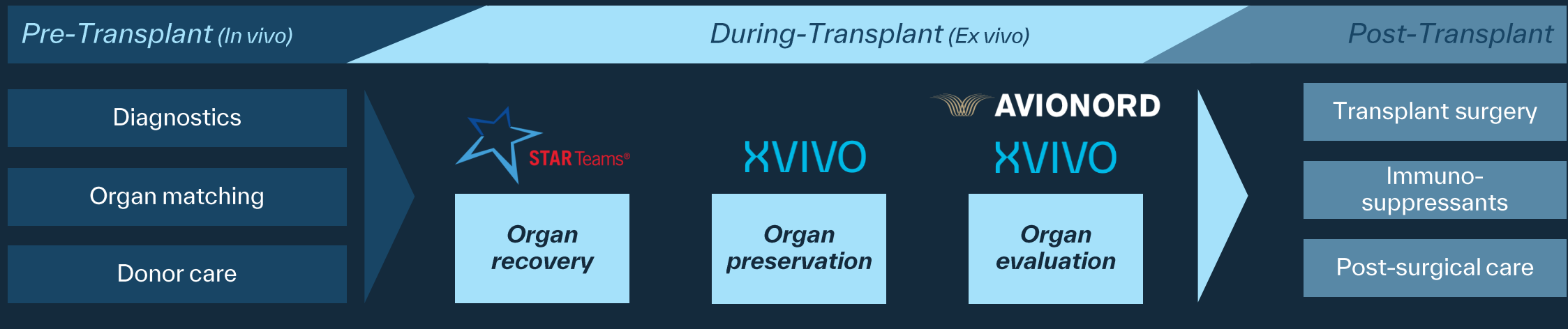
Preferred partner in the transplant process

Accelerate market leadership lungs

New market expansion

Acquisition Update

Acquisitions in the transplant process



STAR teams procurement service ensures surgeons are on call ready to recover organs for transplant centres in the USA

Avionord M&P offer a perfusion service to some of the most prominent abdominal clinics in Italy. Providing critical support, expertise, and experience during machine perfusion.

STAR Teams – Services for organ recovery

At a glance

- U.S. based team of thoracic surgeons, preservationists, and coordinators
- Led by Doctor [Hassan Tetteh](#) – highly reputable thoracic transplant surgeon
- [Subscription based](#) revenue model resulting in more than 400 fly outs in 2021

STAR Teams acquisition

Deal rationale



Enter service segment



High growth business



Extended offer – cross selling synergies

- ✓ Acquisition is well aligned with our overall strategic objectives
- ✓ STAR teams adds service dimension to our strong product portfolio – making more organs available for transplantation

Strategy support



Market leader abdominal



Change the paradigm of heart preservation



Preferred partner in the transplant process



Accelerate market leadership lungs

New market expansion

Avionord Machines & Perfusion

- 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

NOBODY SHOULD DIE WAITING
FOR A NEW ORGAN

Avionord M&P acquisition

Deal rationale



Secure and build Italy



Improve margins and increase revenue per procedure



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

Strategy support



Market leader abdominal

Change the paradigm of heart preservation



Preferred partner in the transplant process

Accelerate market leadership lungs

New market expansion

Digital

XPS Live – analysis of lung transplant data

Why:

Increase confidence in the use of marginal lungs through predictive analytics

What:

Advanced analytics of XPS perfusion data to enable evidence-based decision making

How:

Extended partnership with world-leading Cleveland Clinic

“Solid data-driven analysis combined with personal experience is the way forward to accept more marginal lungs. This partnership with XVIVO will benefit us all”

- Dr. Kenneth McCurry, MD at Cleveland Clinic



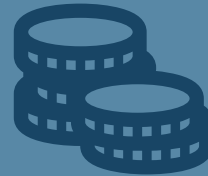
Key take-aways

Services increase
penetration of machine
perfusion

 **AVIONORD**



Services increase
revenue and improve
margins



Services create
customer satisfaction
and retention



Regulatory Strategy

Katrin Gisselfält,
Global Quality Assurance & Regulatory Affairs Director

When can we expect product launch?

- Is the fastest route to market always the best?
- Important to consider and navigate a dynamic regulatory environment - European MDR*
- Expanding to new markets – how and when?

Why a regulatory strategy?



510 (k)/ deNovo

- Faster
- Easier
- Might need clinical data to support
- Showing substantially equivalence
- Can be used as predicate

PMA

- Longer and more complex registration
- Clinical data need to support
- Innovative Technology
- Raised bar for competition - no predicate

XVIVO

has chosen to pursue a PMA route for the innovative hypothermic liver platform: *Liver Assist*



PMA



- Longer and more complex registration
- Clinical data need to support
- Innovative Technology
- Raised bar for competition - no predicate

European MDR

XVIVO

- ✓ Current product range fully on track
- ✓ Kidney Assist Transport MDR certified in March 2022

500,000 devices certified under old directives yet to be converted to MDR

<15%
Currently certified

September
2022

20 Months

Deadline
26 May 2024

New Market Expansion

Background:

The fast growing transplant markets in South America and Asia are important growth drivers in XVIVO's journey to becoming a global all organ company

Focus Markets:

- ✓ *South America – focus on Brazil*
- ✓ *Select Asian Markets – incl. China*
- ✓ *Middle East & Africa*

Our Strategic Objectives

Market Leader Abdominal

Change the Paradigm of Heart Preservation

Preferred Partner in the Transplant Process

Accelerate Market Leadership Lungs

New Market Expansion

Geographic expansion from a regulatory perspective

XVIVO



Full portfolio registered
(Lungs & Abdominal)



Lung Portfolio
(XPS Pending)



Lung Portfolio



- Clinical data from US/EU registrations can (often) be utilized
- CE certificate prerequisite for many registrations

Key take-aways

PMA route secures innovative liver technology



XVIVO well positioned for MDR transition



Product registrations in new markets support strategy



XVIVO Heart technology: The power of oxygenation and the clinical trials

Andreas Wallinder M.D., Ph.D.,
Chief Medical Officer

Change the Paradigm of Heart Preservation

Background:

XVIVO's heart technology can be more than market leading, it has the potential to completely change the standard of care for heart preservation

Definition:

Changing the Paradigm is defined as establishing cold oxygenated perfusion as the standard of care for heart preservation

Key Activities 2022-2024:

- *Trial completion in Europe & ANZ 2023*
- *USA heart trial started 2023*
- *First clinical sales of approved product in 2024 (Europe & ANZ)*

Our Strategic Objectives

Market leader abdominal

Change the paradigm of heart preservation

Preferred partner in the transplant process

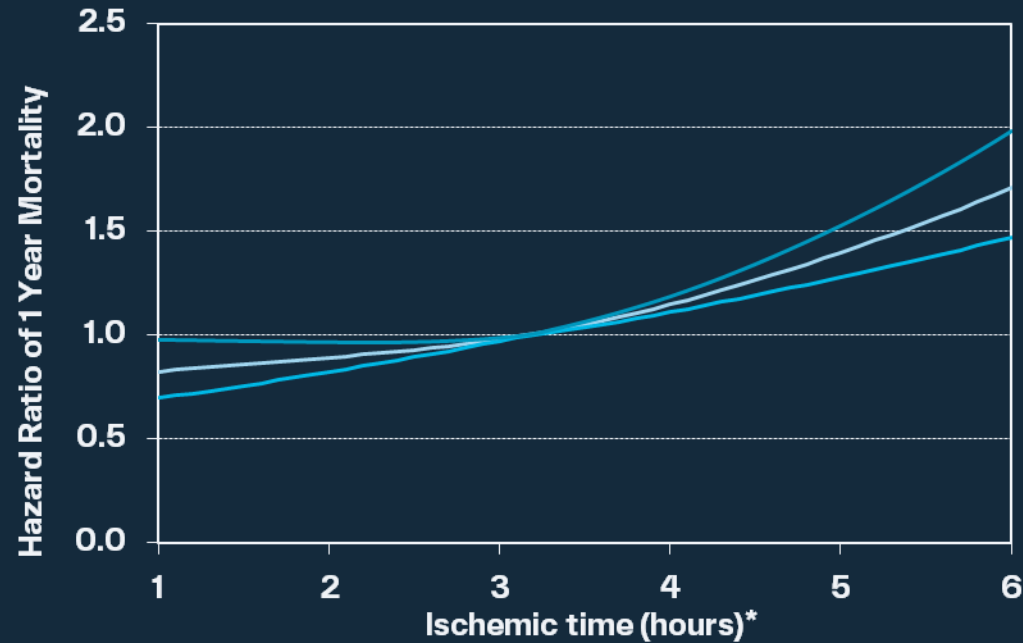
Accelerate market leadership lungs

New market expansion

Strong underlying need that will continue to grow

- ✓ Heart failure affects ~ 64 million people and prevalence is rising due to changing demographics
- ✓ At the final stage, life expectancy is 6- 12 months
- ✓ Heart transplantation is a lifesaving treatment for advanced heart failure, but is limited to a few

Trends in heart donation drives the need for new preservation technology



Donors are older



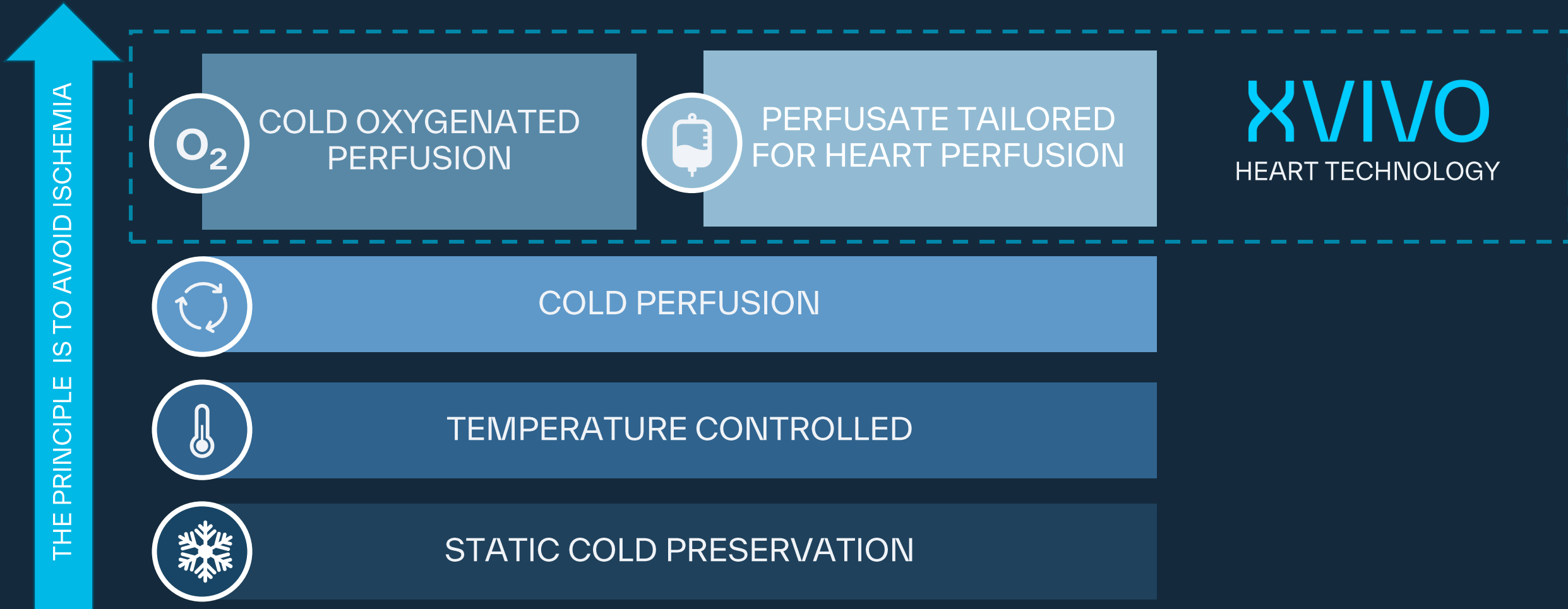
Donors are sicker
(extended criteria)



Donors are located further
from recipients

The need for longer out-of-body times and use of extended criteria hearts requires better preservation methods

Changing the paradigm in heart preservation with new technology



Role of warm heart beating perfusion?

- High **complexity** requiring advanced users
- **No** temperature **safety** net
- Up to 20% **organ loss** during perfusion
- Long-term follow up indicates significantly **worse outcome** than transport on ice ($p = 0.05$)

Warm Perfusion vs. Static Cold Storage



<https://www.fda.gov/media/147298/download>

XVIVO Heart Technology

Continuously **perfusing** the heart with a **cold** (8 °C) **oxygenated** proprietary **solution**

Heart Technology



Disposable Set



Solution and Supplement



XVIVO's novel heart preservation technology



Increased utilization
(Extended criteria donor)



Improved outcomes
(fewer complications, improved survival)



Longer preservation time
(allows for better logistics, longer travel distance,
better matching)



Cost effectiveness



XVIVO Clinical Trial Programs



	EUROPE	AU/NZ	LUND	US
<i>Status</i>	Ongoing	Ongoing	Ongoing	Start 2023
<i>No of centers</i>	15	5	1	up to 15
<i>Population</i>	Standard & EC*	6-8 hours	Standard & EC	EC
<i>No of patients</i>	202	36	68	TBD

*Extended Criteria

Geographical coverage in clinical trials

- well equipped for launch

- The clinical trial sites in Europe alone perform >600 heart transplants annually
- 40% of donor hearts in Europe have an ischemic time of more than 4 hours
- Trial sites express strong interest in post trial use for long transports, extended criteria donor and potentially standard donor hearts



Heart Transplantation in the USA

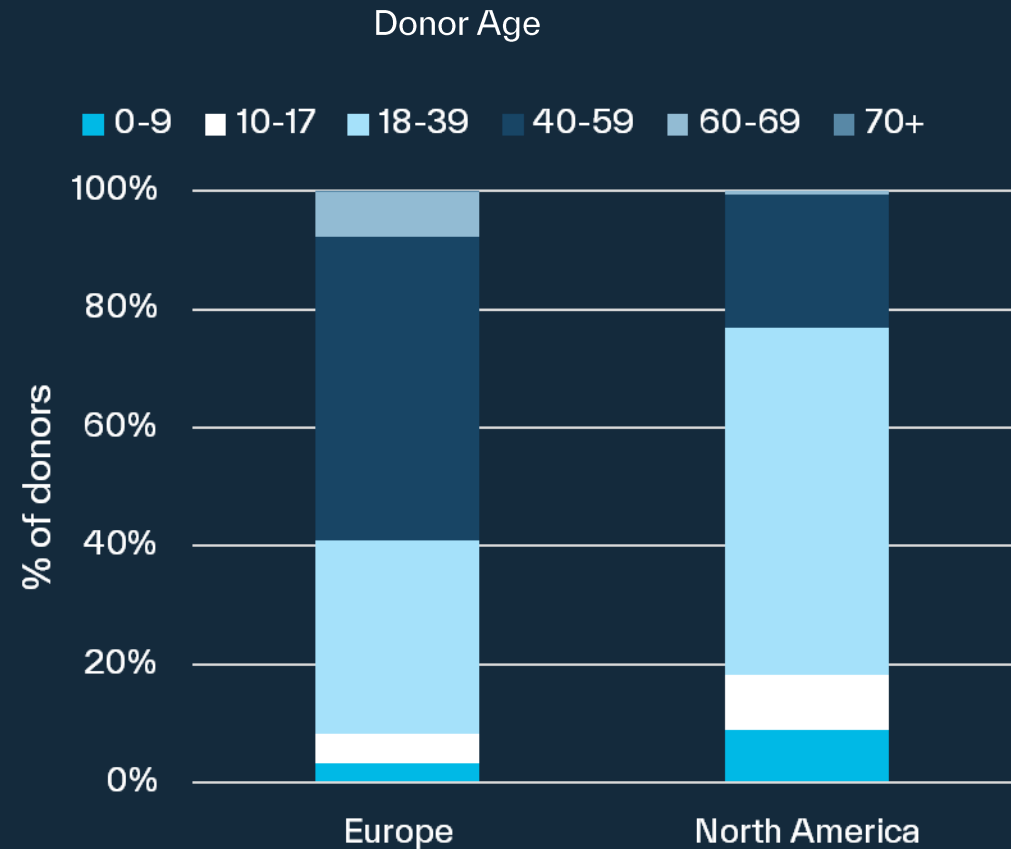
Jaya Tiwari,
Vice President Clinical & Regulatory Affairs USA

Heart donors: Europe vs. USA

Donor **age** and heart transport time are the key differences between Europe and USA

Despite transplanting more hearts than Europe combined...

the US rarely utilises donor hearts above 40 years of age

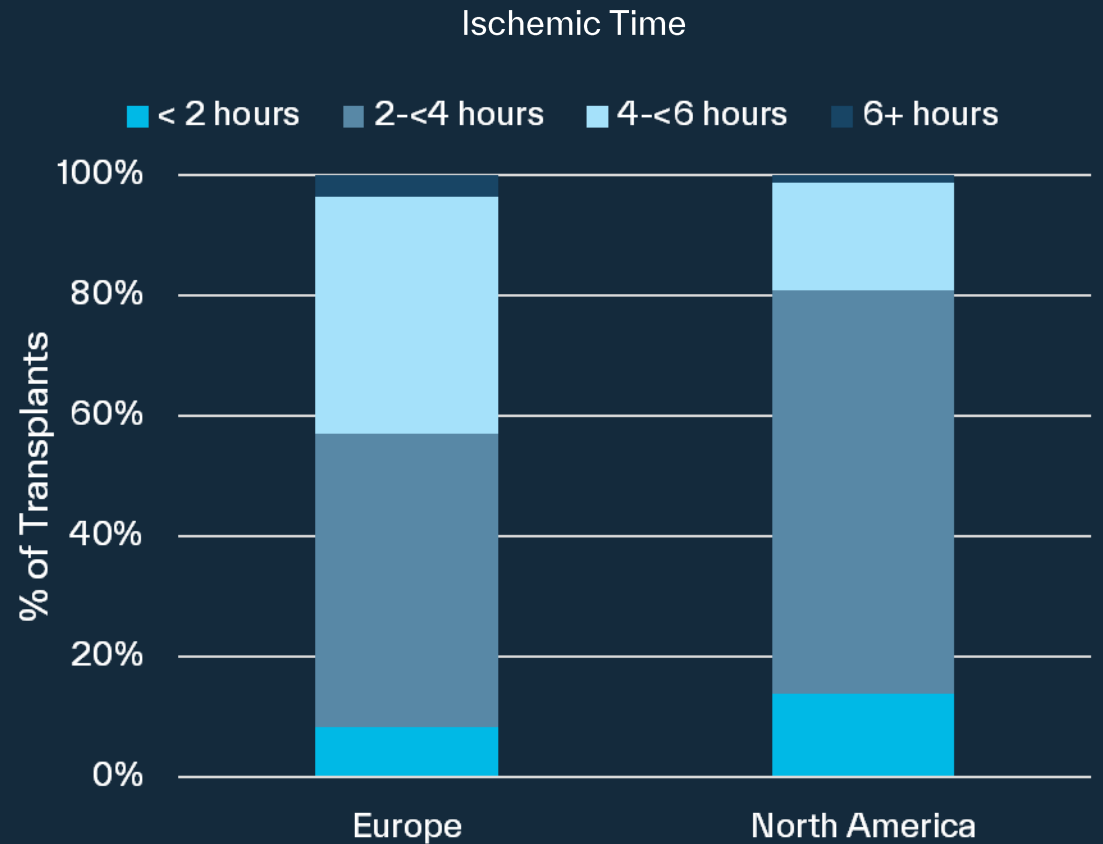


Heart donors: Europe vs. USA

Donor age and heart **transport** time are the key differences between Europe and USA

Despite transplanting more hearts than Europe combined...

the US utilises few hearts from donors with an out-of-body time above 4 hours, compared to Europe



The critical need for increased utilization

Non-Acceptance Reasons



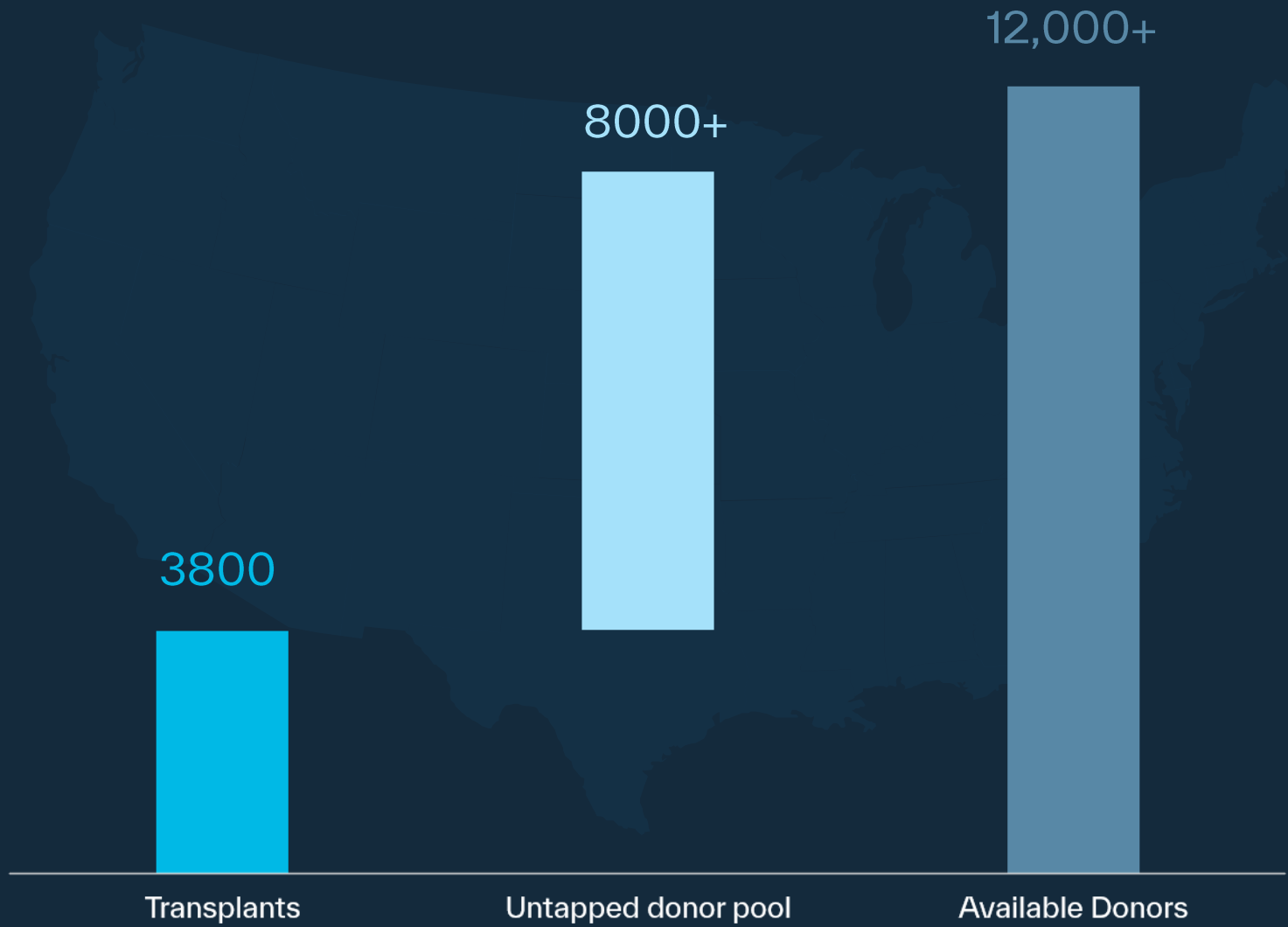
Age



Transport Time

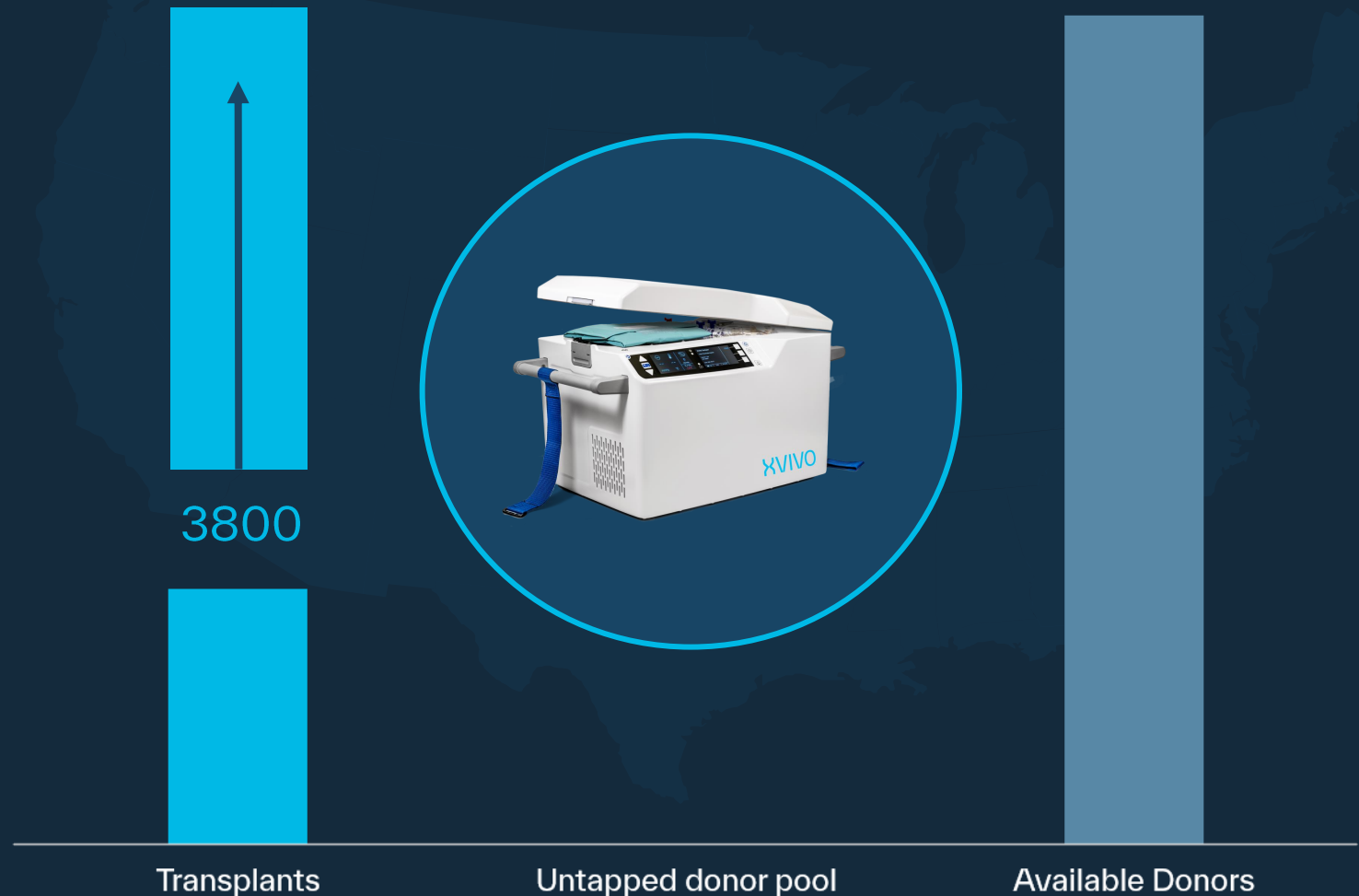


Marginal Organ Quality



The critical need for improved preservation

XVIVO Heart Technology is uniquely suited to address the most common reasons for organ turn-down and allow hospitals to safely utilize organs from older donors and with longer transport times.

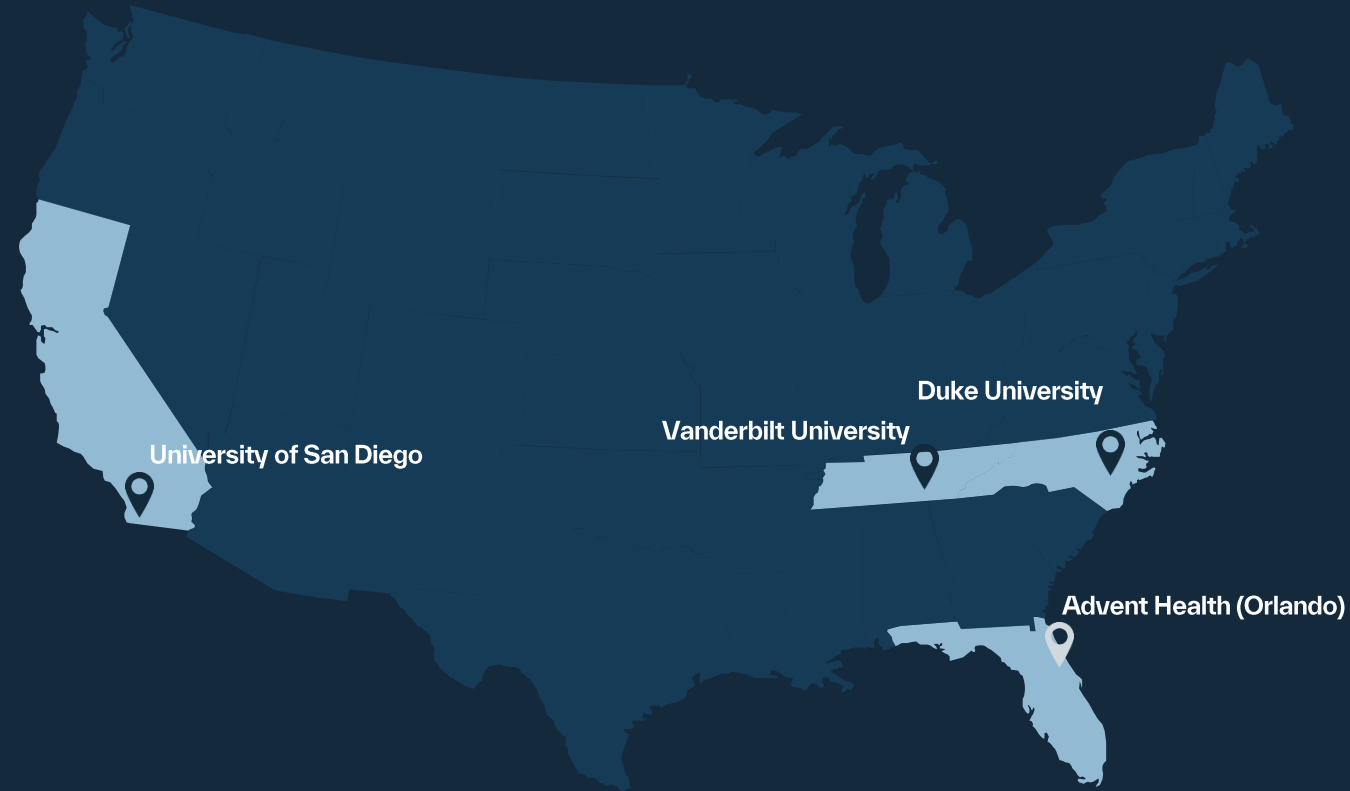


US trial “PRESERVE” will broaden device indications

- A Prospective, Multi-center, Single-Arm, Open-Label Study of Hearts Transplanted after Non-Ischemic Heart PRESERVation from Extended Donors
- Inclusion/exclusion criteria addresses critical need
 - Longer transport times
 - Older donors
 - Marginal quality organs
- Trial start 2023

US trial will engage up to 15 trial centers

- High interest in XVIVO heart technology
- Collaborations underway with high volume centres, including 4 out of the top 8 centres in the USA:
 - *Vanderbilt University*
 - *Duke University*
 - *University of California San Diego*
 - *Advent Health (Orlando, FL)*



XVIVO ...

- ... is in 90% of thoracic transplant centers
- ... clinical trial program creates foundation for regulatory approvals covering 80% of global market
- ... has 35 world leading heart transplant centers involved in clinical trial program
- ... including all heart transplant centers in Australia and New Zealand



Capital markets day summary and Q&A session

>30% EBITDA

>20% EBIT

>70% Gross Margin on Abdominal Portfolio



2x Installed machine base



20% Penetration of EVLP



15% of global sales from new markets



Nobody should
die waiting for a
new organ

