

WELCOME TO

# HealthInvest

April 2025



**EM**VISION

**MiCROBA**<sup>™</sup>

ortho·cell

 **LUMOS**  
DIAGNOSTICS

 **Dimerix**

PRESENTED BY:  **ir department...**  **morgans**

MEDIA PARTNER: **STOCKHEAD**



Your Co-Host

**JANE LOWE**

FOUNDER & MANAGING DIRECTOR

ir department...





Your Co-Host

SCOTT POWER

SENIOR ANALYST



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Presenter

**SCOTT KIRKLAND**

CEO AND MANAGING DIRECTOR



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emvision.com.au

ASX:EMV

# HEALTHINVEST PRESENTATION

APRIL 2025

ASX:EMV



**emu**<sup>TM</sup>  
Bedside Scanner



**First Responder**  
Pre-hospital scanner



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# INVESTMENT THESIS OVERVIEW



- Founded in 2017 to advance and commercialise a decade of groundbreaking research out of the **University of Queensland**.
- EMVision has two distinctive portable brain scanner products to deploy in-hospital (**emu™**) or in the field (**first responder**) to enable earlier diagnosis and earlier triage, transfer or treatment decisions
- First indication targeted for **stroke care**, a leading cause of global disability and **multi-billion-dollar market opportunity**, with a second planned indication in **traumatic brain injury**.
- Over **\$50m invested** in ‘**world first**’ product development since inception, including approximately \$20 million of funding from **non-dilutive grants**.
- Executed several best-in-breed **clinical and industry collaborations**, including strategic investment from **Keysight Technologies (NYSE:KEYS)** and industry partner of the **Australian Stroke Alliance**.
- **Well funded** to execute clinical program with **\$15.78m proforma cash 31 Dec**

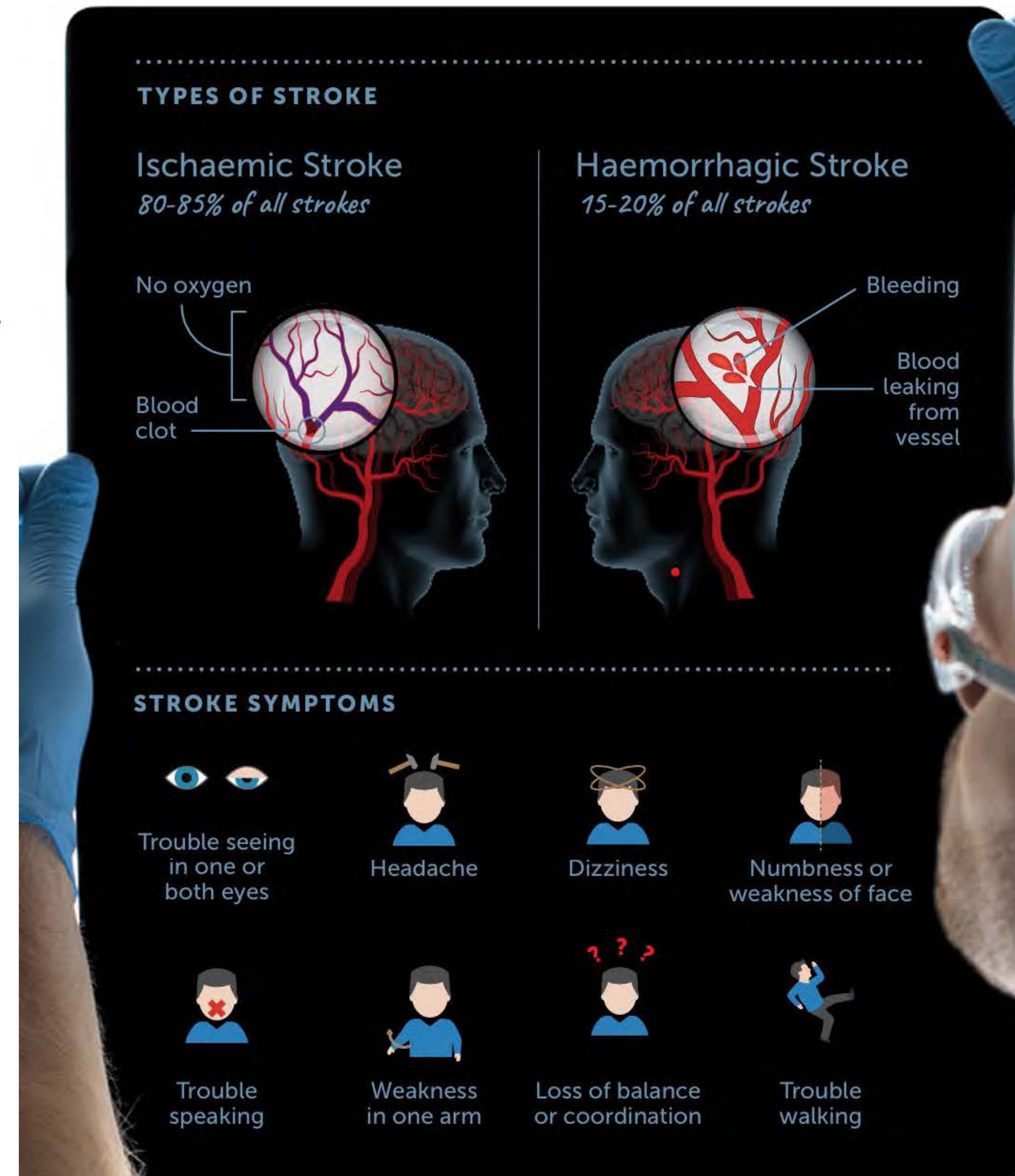




## WHY ARE WE STARTING IN STROKE?

- **1 in 4 adults will suffer from a stroke** in their lifetime<sup>1</sup>.
- **60% of stroke patients suffer permanent disability** after their stroke<sup>2</sup>.
- The **annual economic impact** of stroke currently represents 0.66% of global GDP, **estimated to exceed US\$1 trillion by 2030**<sup>1</sup>.
- **‘Time is brain’**, 1.9 million brain cells die every minute during a stroke. Treatment requires stroke type differentiation first.
- Treatment within 3 hours of symptom onset, particularly the first **‘golden hour’**, **greatly improves chances of recovery** with little or no disability.

1. World Stroke Organisation
2. Poomalai et al., *Functional Ability and Health Problems of Stroke Survivors*, 2023
3. Rai et al., *Updated estimates of large and medium vessel strokes, mechanical thrombectomy trends...*, 2022
4. Mikulik et al., *Stroke 20 20: Implementation goals for intravenous thrombolysis*, 2021
5. Graphic source – RFDS





# CT SCANNERS ARE VITAL IN STROKE CARE, BUT ARE NOT READILY AVAILABLE AT THE POINT-OF-CARE



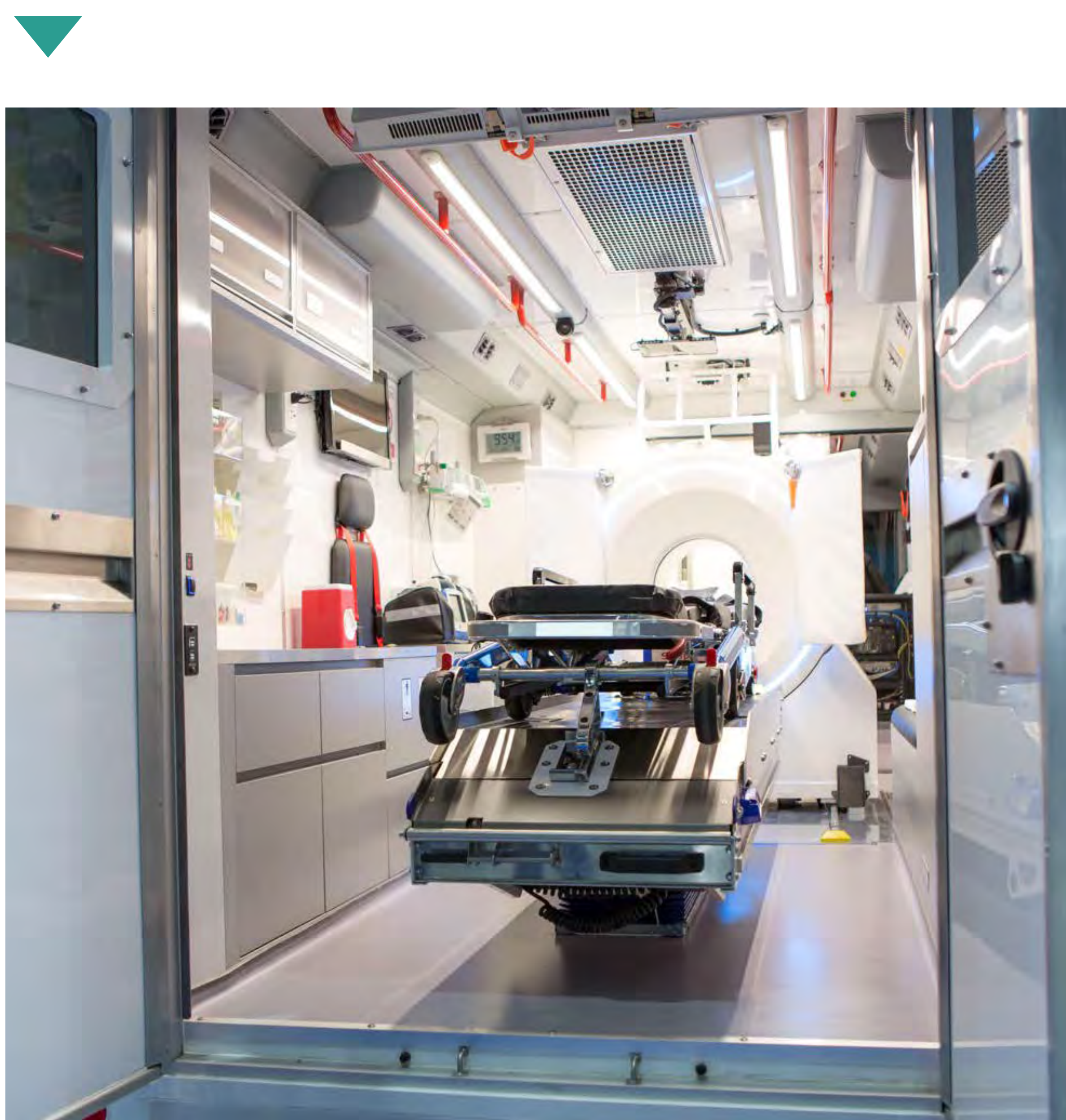
*CT scanners cannot be widely deployed at the bedside, or in remote locations, or in every ambulance.  
EMVision's products can address this unmet need.*



## Conventional CT

1,800 – 2,700 kg  
Fixed, hospital-only  
Ionizing radiation  
Specialist operator  
\$\$\$\$\$

Mobile Stroke Units (MSUs) are custom-built ambulances fitted with a mobile CT



## Mobile CT Scanner

450 – 1,000 kg  
Mobile  
Ionizing radiation  
Specialist operator  
\$\$\$\$\$

880 mm

**emu™**

100 kg  
Portable, in-hospital  
Non-ionizing  
Trained healthcare professional  
\$\$

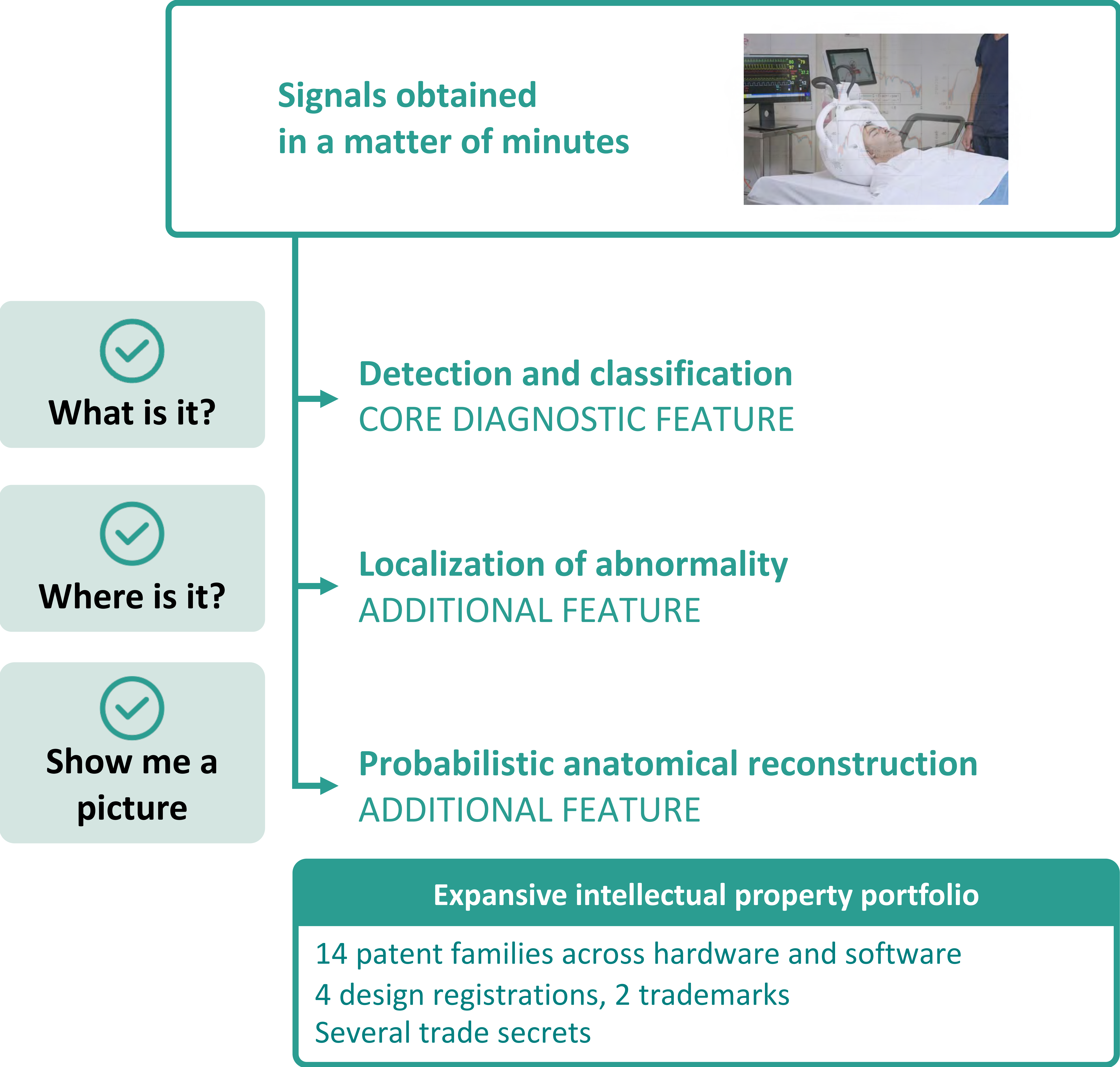
430 mm

**First Responder**

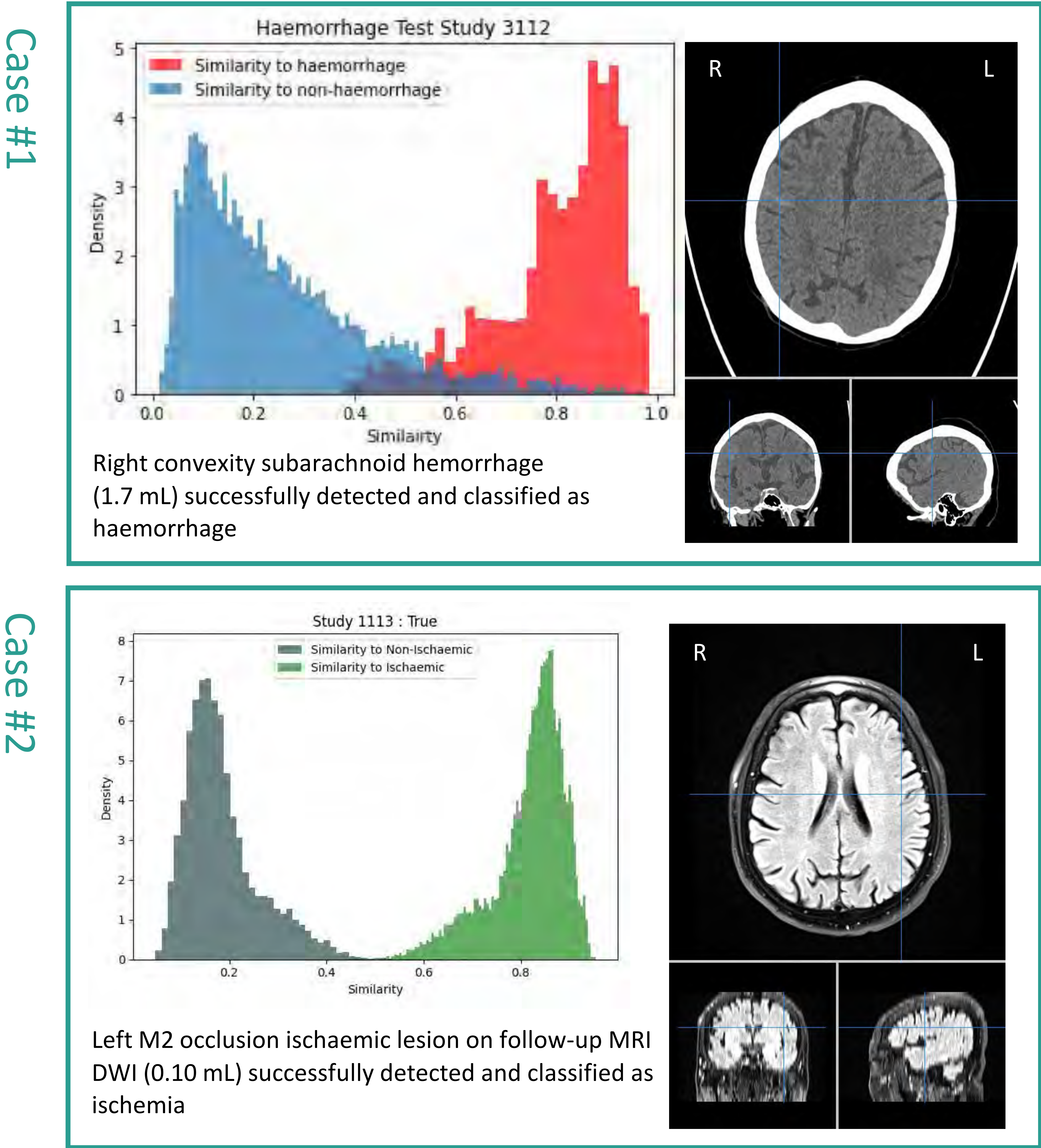
< 12 kg  
Portable, pre-hospital  
Non-ionizing  
Trained healthcare professional  
\$



Algorithm portfolio



Very encouraging detection capabilities





# ACCESSIBLE NEURODIAGNOSTICS AT EVERY STAGE



EXAMPLE STROKE  
PATIENT PATHWAY

**STROKE SYMPTOMS**  
Remember, recognize and act fast

**Stroke Symptoms**

0 to 2.5 hours

**Emergency Response**

< 2.5 hours

**Hospital Arrival**

< 4 hours

**Triage and Imaging**

< 4 hours

**Acute Treatment**

< 24 hours

**Post-Acute Care and Discharge**

> 3 weeks to lifetime

Time since LSW  
(Last Seen Well)

First commercial product

emu™

Second commercial product

First Responder

POTENTIAL CLINICAL  
USE-CASES

## First Responder

- Positively **identify hemorrhages** for pre-hospital **blood pressure management**.
- **Reliably distinguish between haemorrhagic and ischaemic strokes**, opening the door to potential in-field thrombolysis opportunities.
- **Reliably identify potential endovascular clot retrieval or neurosurgery candidates**, assisting decision-making on transfer to appropriate comprehensive stroke-capable hospitals.



## emu™

- **Front-line decision support where there is limited access to CT imaging (e.g., in rural and remote areas)** to inform patient triage and transfer decision-making (e.g. direct to angio)
- **Keep a closer eye on potential complications** and monitor patients following therapy or surgical intervention.
- Detect **secondary bleeding earlier**.
- Identification of **post-operative stroke**.



**Ultimately reducing time from symptom onset to treatment or intervention is a key objective.**

EMVision's portable solutions deliver rapid neurodiagnostic capabilities across diverse settings, ensuring timely triage, transfer or treatment decision making.  
The EMVision products are not designed to replace CT but fill a gap where CT are not immediately available.



# FIRST RESPONDER SCANNER IN THE SKIES

Pre-hospital aeromedical environment testing has commenced



Several volunteer scans have been successfully completed with EMV's First Responder PoC scanner in Port Augusta, Marla and Maree, South Australia in collaboration with the RFDS and the Australian Stroke Alliance.

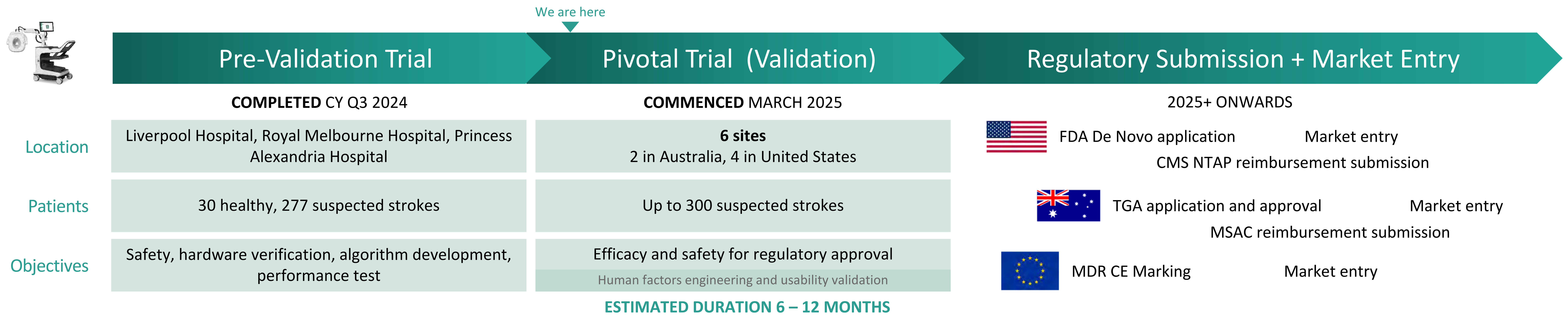


# emu and First Responder

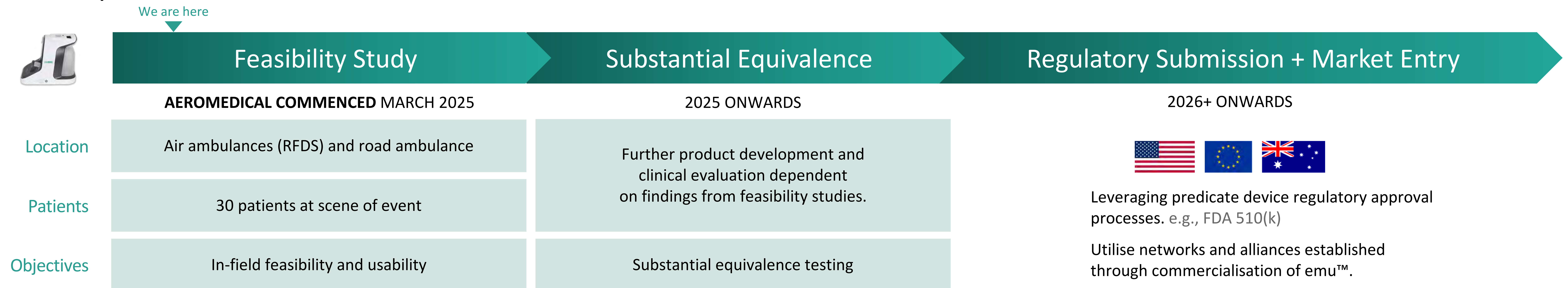
## OUR PATH TO MARKET ENTRY



**emu** First commercial product



First Responder    Second commercial product



Roadmaps are indicative and subject to change.



# MARKET OPPORTUNITY



## Attractive Revenue Models

Traditional CapEx or innovative OpEx selling model offerings to provide buyer flexibility through direct or distributor sales channels.

### emu

#### Capital equipment and consumables model

- Capital Equipment  
Target of ~US\$175,000
- Consumables (disposable cap, coupling media)  
Target of ~US\$25 / per scan
- Preventative maintenance & service contracts  
Target of ~10% of capital equipment p.a.
- Software upgrades (including additional indications)

#### Monthly subscription model

- Target ~US\$8,000 / month (subject to term)
- Delivery of the unit and training
- Consumables (subject to quota)
- Software upgrades
- Potential integration into PACS and EMR
- Access to cloud storage and viewing
- Routine maintenance included

Significant consumable opportunity for both emu and First Responder point-of-care brain scanners.

emuconsumables ~US\$25 / per scan

Coupling media Disposable cap

First Responder consumables ~US\$50 / per scan

## Total Addressable Market

emu ADDRESSABLE MARKET ~\$15B			
US	GER, FRA, UK	AUS	ROW
10,200	5,960	545	86,000

Market estimates are calculated on the assumption deployed per relevant department (e.g., emergency department, stroke ward, ICU)  
Key Targets

1,600 PSC/CSC	642 PSC/CSC	93 PSC/CSC	
---------------	-------------	------------	--

CSC = Comprehensive Stroke Centre, PSC = Primary Stroke Centre

1,300 Critical Access Hospitals (CAH) in the US:  
< 25 inpatient beds, average < 96 hours inpatient stay, located > 35 mi from other hospitals.  
Unique reimbursement (allowable costs plus 1% reimbursement)

First Responder ADDRESSABLE MARKET			
US	GER, FRA, UK	AUS	ROW
60,000	58,000	5,200	54,000
Road and aeromedical ambulances			

EMV cautions investors that there are regulatory barriers and unique access challenges to each market and can be subject to varying rates of penetration. Addressable market sources: estimates based on ABS, U.S Census Bureau, WHO, AHA, EMS data and other publicly available data.. There are further regulatory hurdles to sell into the rest of the world (e.g., China, Japan, Brazil, Mexico, South Korea, Spain, Italy, India and Canada)



# CAPITAL STRUCTURE

## ASX TICKER: EMV

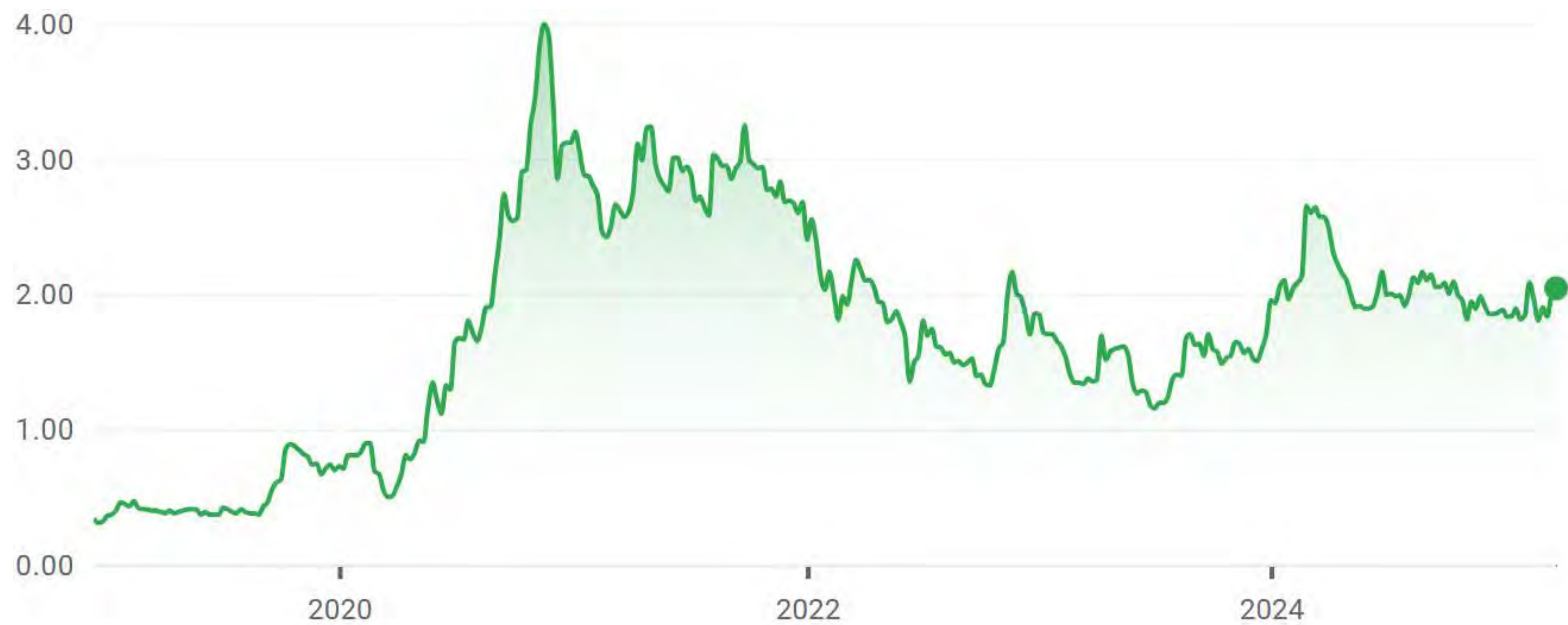
### Headquarters

4.01, 65 Epping Road,  
Macquarie Park  
Sydney, Australia



### Substantial shareholders

Keysight Technologies (NYSE:KEYS)  
– 8.7%  
Scott Kirkland (CEO) – 5%

Share Price (28 <sup>th</sup> March 2025)	\$2.04 AUD
Shares on issue	85,516,535
Total Options on issue	3,900,000
Market Capitalization	\$174.4m AUD
Enterprise Value	\$158.7m AUD
Proforma Cash balance (31 <sup>th</sup> Dec 2024)	\$15.7m AUD
Remaining non-dilutive staged grants	\$0.8m AUD




## KEY 2025 CATALYSTS


- 

Pivotal (validation) trials

First Responder

Pre-hospital road and air trials

*Activation, recruitment, and reporting*
- 

Establishment of go-to-market partnerships and strategic relationships
- 

Regulatory submissions for approvals in major markets





# HealthInvest April 2025

#HealthInvest



Presenter

**DR LUKE REID**

CHIEF EXECUTIVE OFFICER

**MICROBA™**



**#HealthInvest**

**HealthInvest April 2025**



**MICROBA<sup>TM</sup>**

# **At the forefront of microbiome diagnostics & therapeutics**

HealthInvest 2025

**ASX: MAP**  
**2 APRIL 2025**

Authorised for release by CEO & Chairman



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## SECTION 1

# The Microbiome Opportunity

The next frontier in precision healthcare



# Chronic diseases remain difficult to diagnose, treat, manage and cure



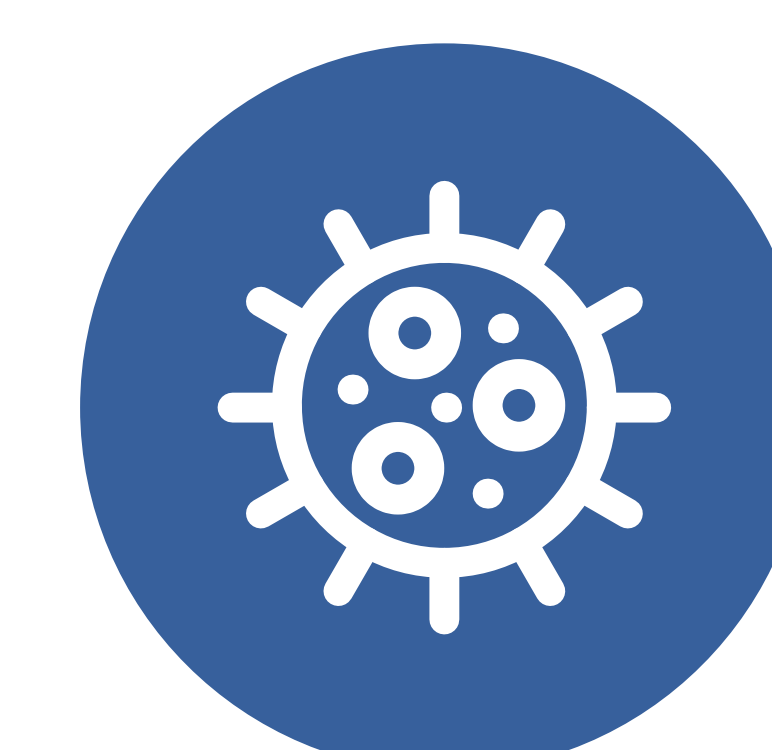
Gastrointestinal



Mental



Cardiovascular



Cancer



Autoimmune



Allergy



Chronic diseases collectively represent over  
**90% of healthcare spend in the US.**



## US\$4 Trillion

Ninety percent of the nation's US\$4.5 trillion in annual health care expenditures are for people with chronic and mental health conditions\*



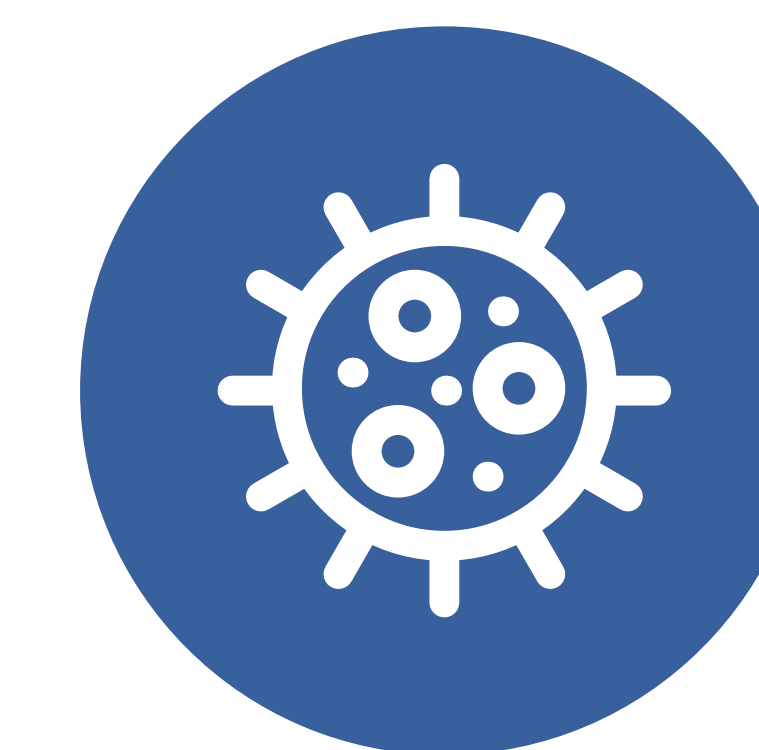
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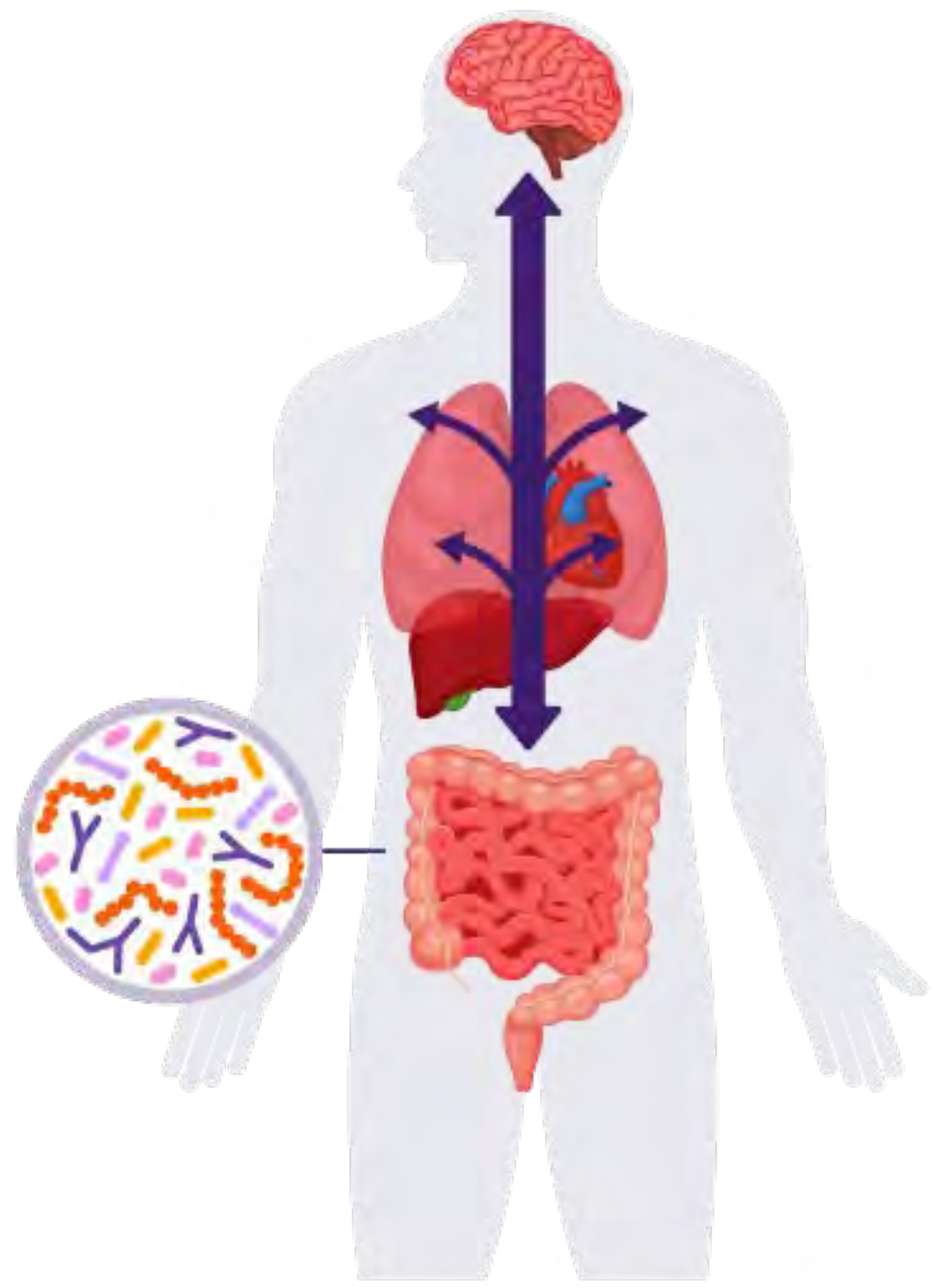
Autoimmune



Allergy



The **gut microbiome** is **implicated** in all of these conditions.



**21,000+**

Research publications demonstrate a clear link between chronic diseases and the gut microbiome\*



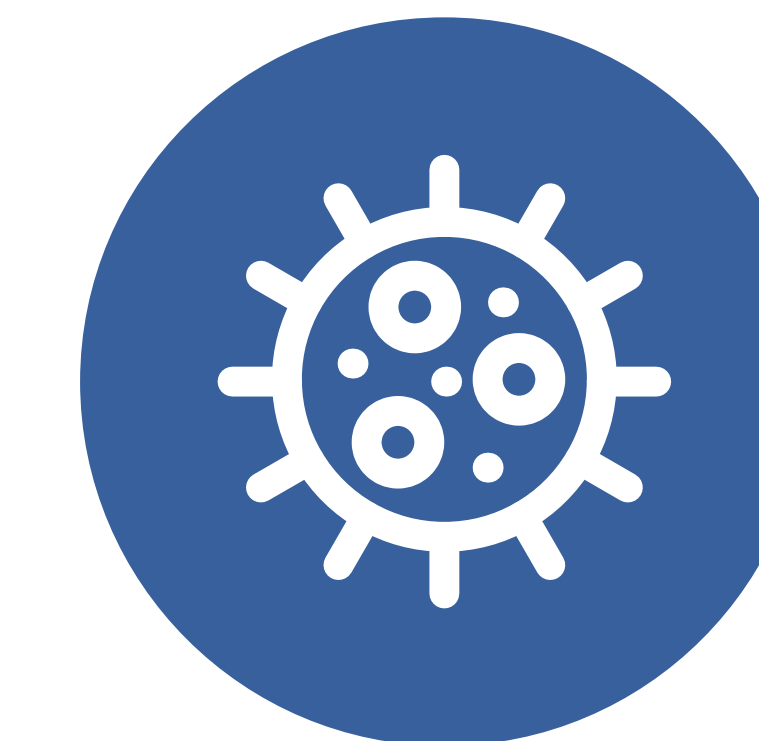
Gastrointestinal



Mental



Cardiovascular



Cancer



Autoimmune



Allergy



# Changing the gut microbiome can treat chronic disease.



## 150+

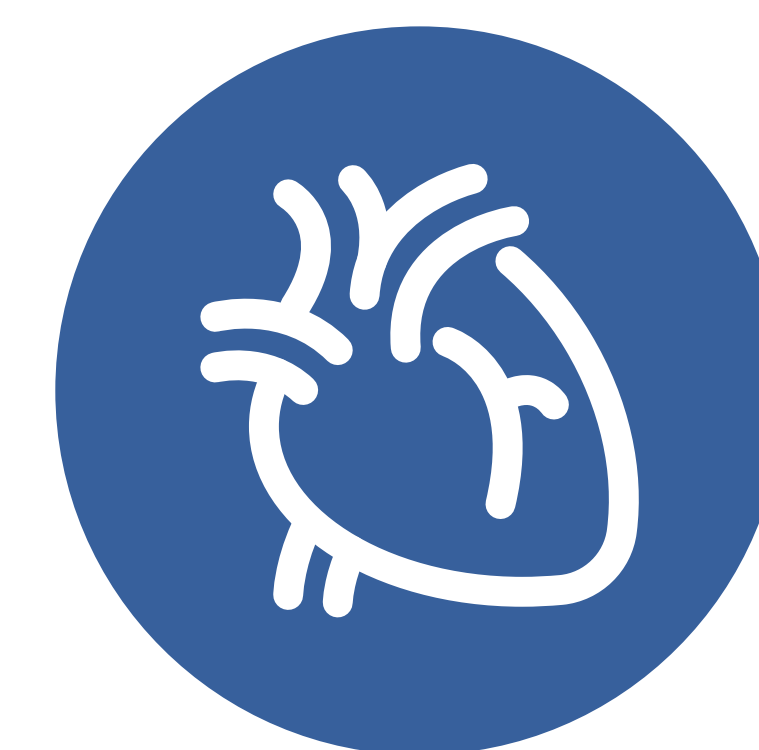
Global clinical studies demonstrate that microbiome modulation can influence disease outcomes and clinical symptoms\*



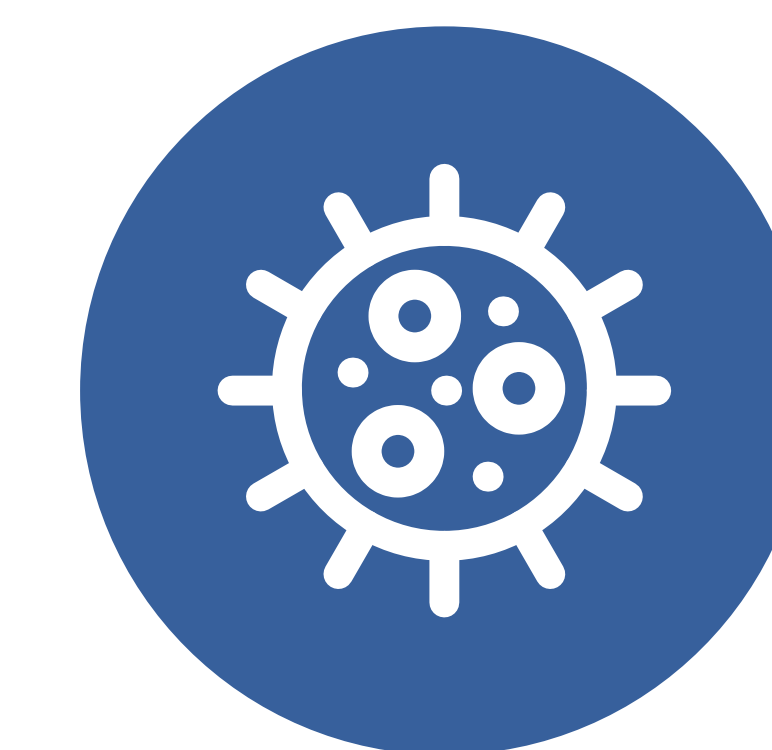
Gastrointestinal



Mental



Cardiovascular



Cancer



Autoimmune



Allergy

PubMed search terms "gut microbiome" and "modulate" and "clinical study" and manually selecting for clinical trials with positive results indicated in the abstracts.



# Combating chronic disease through microbiome diagnostics and therapeutics

## \$1.4 trillion healthcare disruption opportunity



Microbiome testing to diagnose and match patients  
with the right treatment

**\$125B** Est. TAM



Microbiome therapy to treat  
chronic diseases

**\$1.3T** Est. TAM

Management estimate based on desktop study of the total number of patients across the top 10 chronic diseases impacted by the microbiome, across the United States, United Kingdom, Australia, France, Germany, Spain & Italy. Conservative diagnostic and therapeutic pricing in USD applied based on existing predicates.



“Our partnership with Microba exemplifies our commitment to invest in cutting edge developments in laboratory medicine. We see microbiome testing becoming a key part of pathology over coming years and are excited about the potential of this partnership and the opportunities that Microba's technology will provide for Sonic’s global operations, our referring clinicians and our patients.”

**Dr Colin Goldschmidt – CEO, Sonic Healthcare**





SECTION 2

# Why Microba?

The world's leading clinical Microbiome company



# Microba is the **world's leading *clinical Microbiome company*** - proven science & real patient outcomes



Deep bench of world-class leaders



Clear, global & ambitious vision



Family of mutually-reinforcing businesses



Proprietary technology - powered flywheels



Impact and growth-oriented cultural values



# Clear, global and ambitious vision



## **Broad-based acceptance**

The microbiome is recognised by healthcare professionals and patients as critical to health and disease management.



## **Regular testing is commonplace**

High quality and clinically useful microbiome testing is performed regularly – initiated both by patients and clinicians.



## **Usage of approved therapeutics is routine**

Microbiome therapeutics are approved and in routine use for both maintenance and the treatment of multiple chronic diseases.



## **Millions of patients living healthier lives**

Microbiome diagnostics and therapeutics have materially improved millions of patient lives – driving yet further awareness and adoption.



SECTION 3

# Microba's Diagnostics

A vision for improved patient health outcomes at scale



# Our diagnostics focus

Patients suffering from gastrointestinal disease



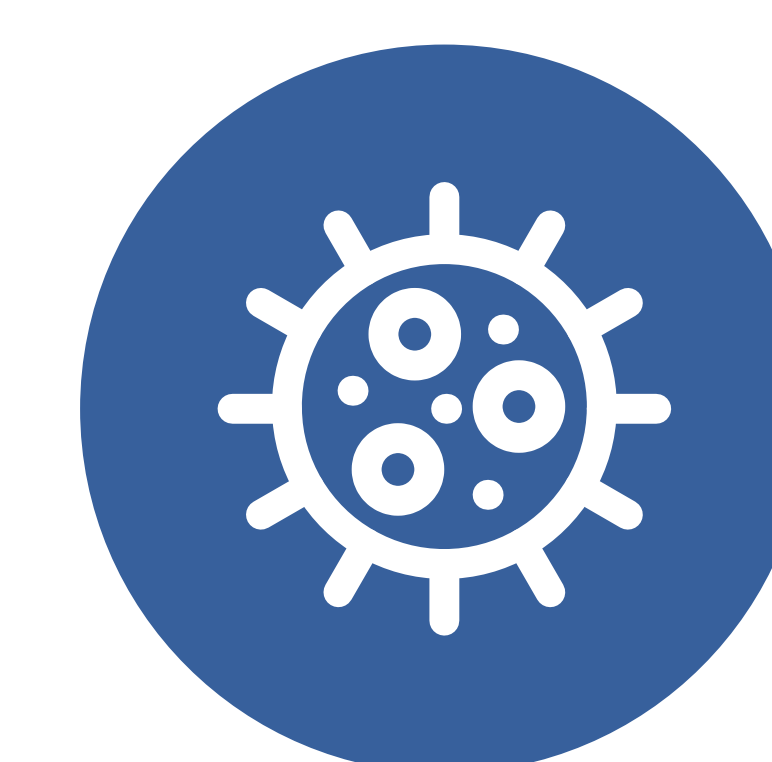
**Gastrointestinal**



Mental



Cardiovascular



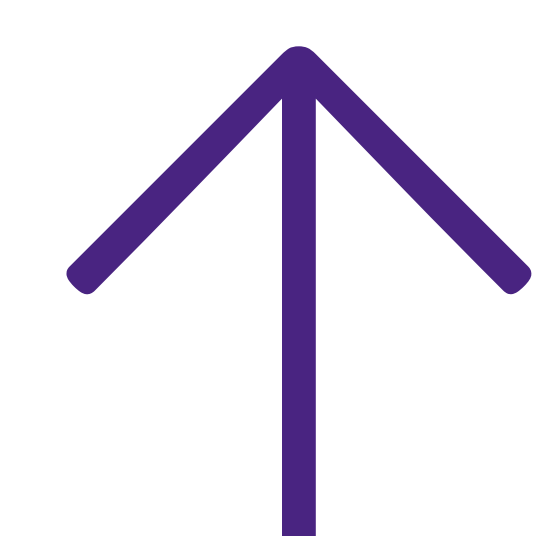
Cancer



Autoimmune



Allergy



Focusing, and solving this first will then enable us to advance to the next problem



# Why Gastrointestinal Disease?

Millions of patients affected. Half are not getting a resolution

## 37,310,000

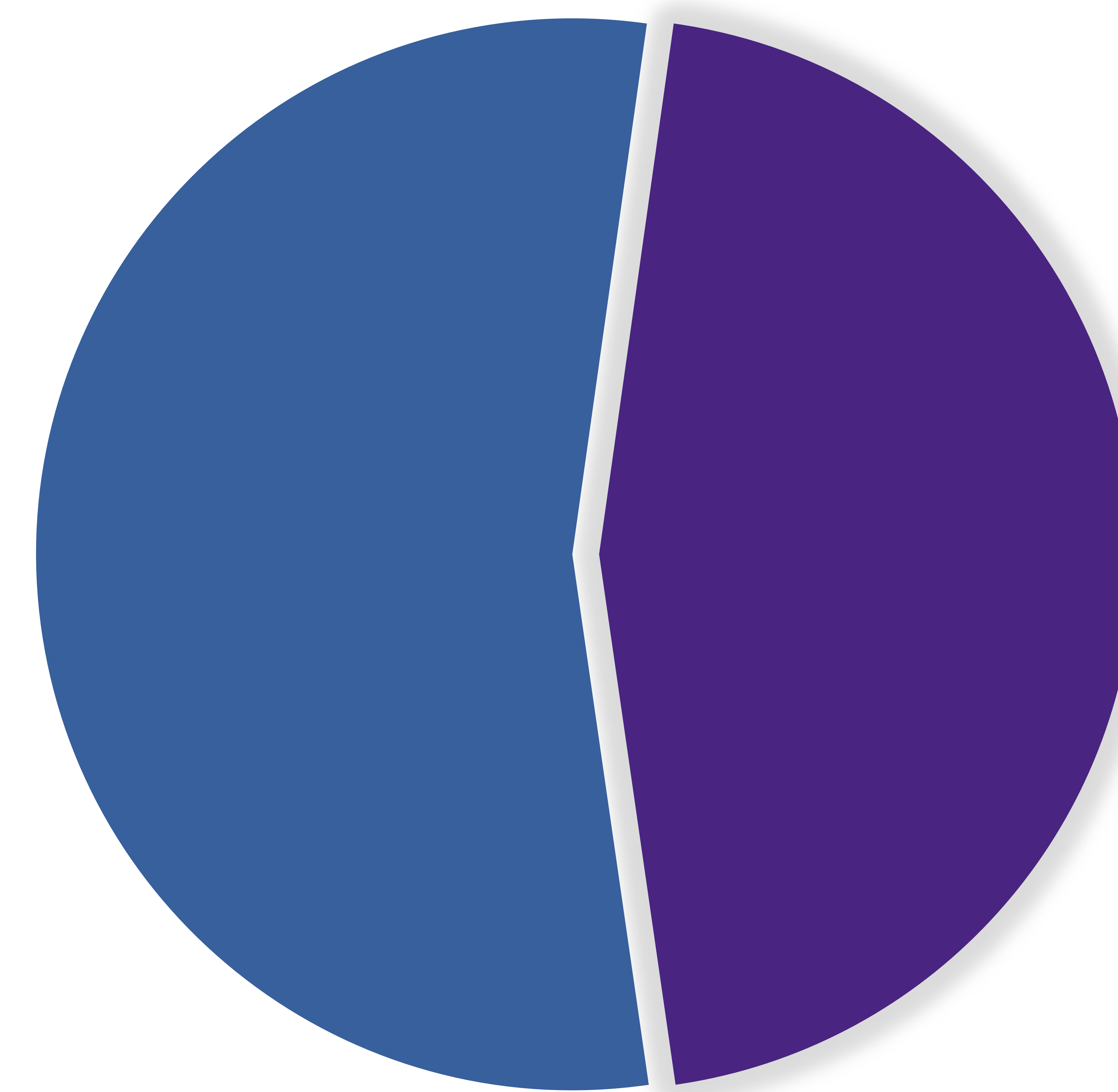
**Patients** presenting annually in the US  
with lower GI abdominal symptoms\*

21,500,000  
Pain, bloating, other

15,370,000  
Diarrhoea

440,000  
IBD

53%  
Resolved



47%  
Unresolved

% of patients achieving resolution of gastrointestinal  
symptoms after 5 years\*\*

\* Assessment of Medicare claims analysis. Estimated Private and Medicaid numbers extrapolated from Medicare claims analysis completed with Boston based MedTech specialist consultancy Veranex Inc.

\*\* Gordon, J., Miller, G., & Valenti, L. (2015). The management of unresolved gastrointestinal symptoms in Australian general practice. *Australian Family Physician*, 44(9), 621-623



# Microba's current comprehensive diagnostic products 16

## lead the market in **addressing this problem head-on**

### First line

Diagnosing  
pathogenic causes  
of GI symptoms

### Gastrointestinal pathogen test

**Launched March 2024 – Currently sold to Medical Clinicians**

- ✓ Stool DNA test.
  - ✓ 175 targets.
  - ✓ Expertly curated clinical recommendations for targeted treatment.
- 

### Second line

Identifying functional  
causes and treatment  
options for  
non-pathogenic  
GI symptoms

### Gastrointestinal disorder test

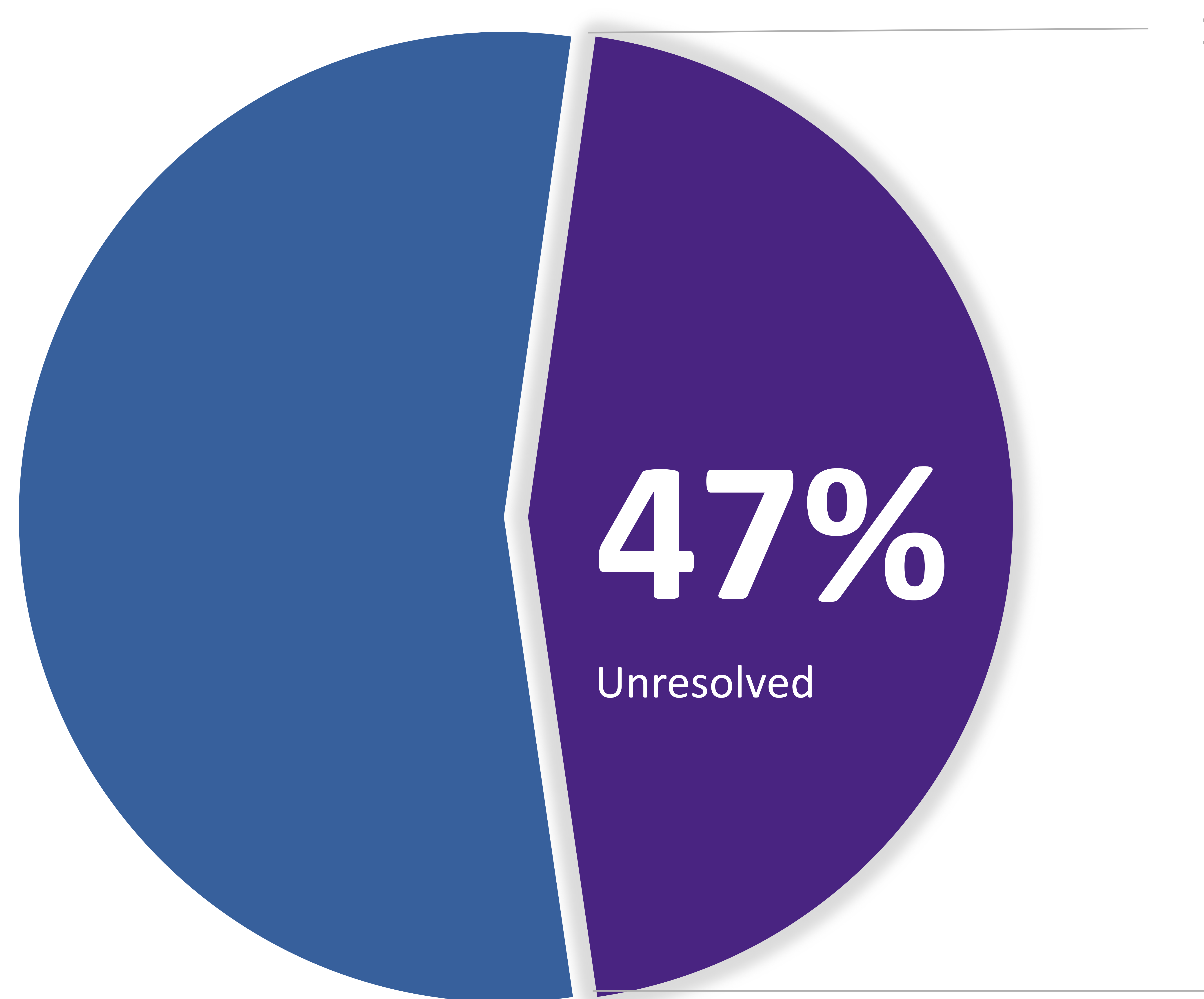
**Launched February 2023 – Currently sold to IFM Clinicians**

- ✓ Stool DNA + targeted biomarker test.
- ✓ 7 functional GI markers. >28k microbiome markers.
- ✓ Expertly curated clinical recommendations for personalised treatment.

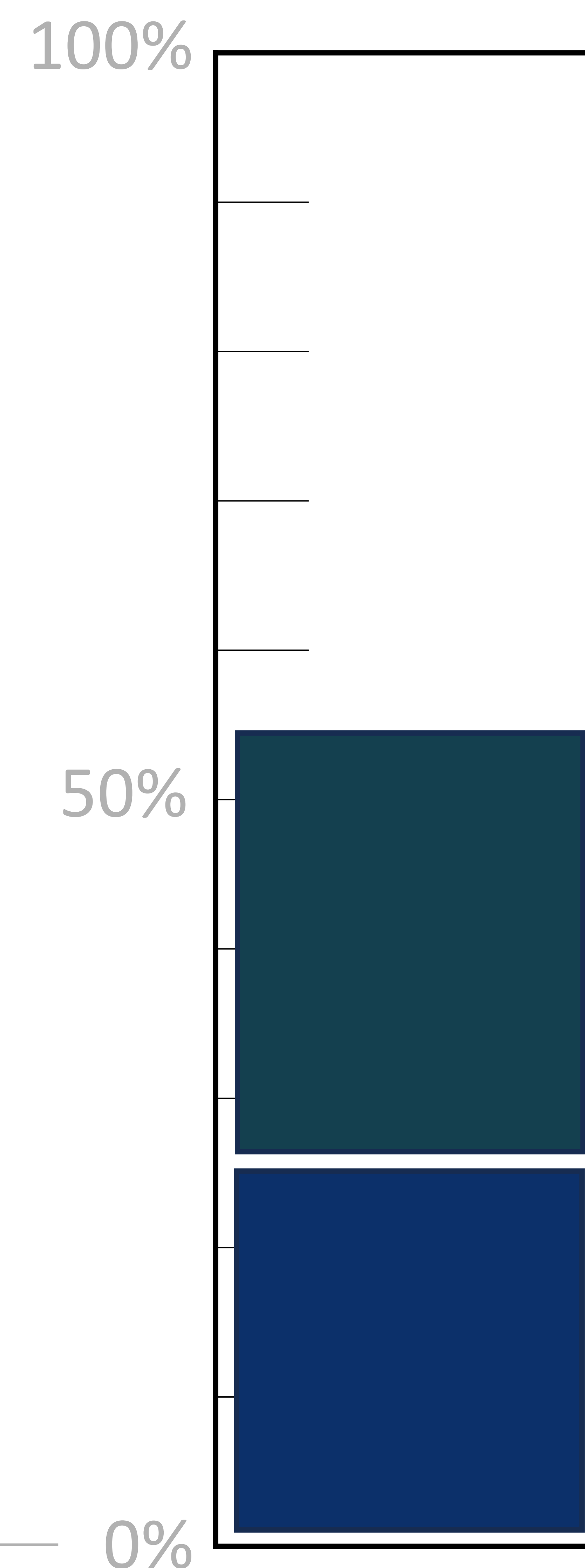


# Getting answers for patients in need

Microba's diagnostic products are closing the gap on GI symptom diagnosis and treatment



% of patients achieving resolution of gastrointestinal symptoms after 5 years



**28%\*** new insights with **MetaXplore™**

**24%\*\*** new diagnoses with **MetaPanel™**

**52%** receiving critical new diagnoses and treatment recommendation for these patients.

\* Study of first 17 months of MetaXplore test results in clinical practice in Australia

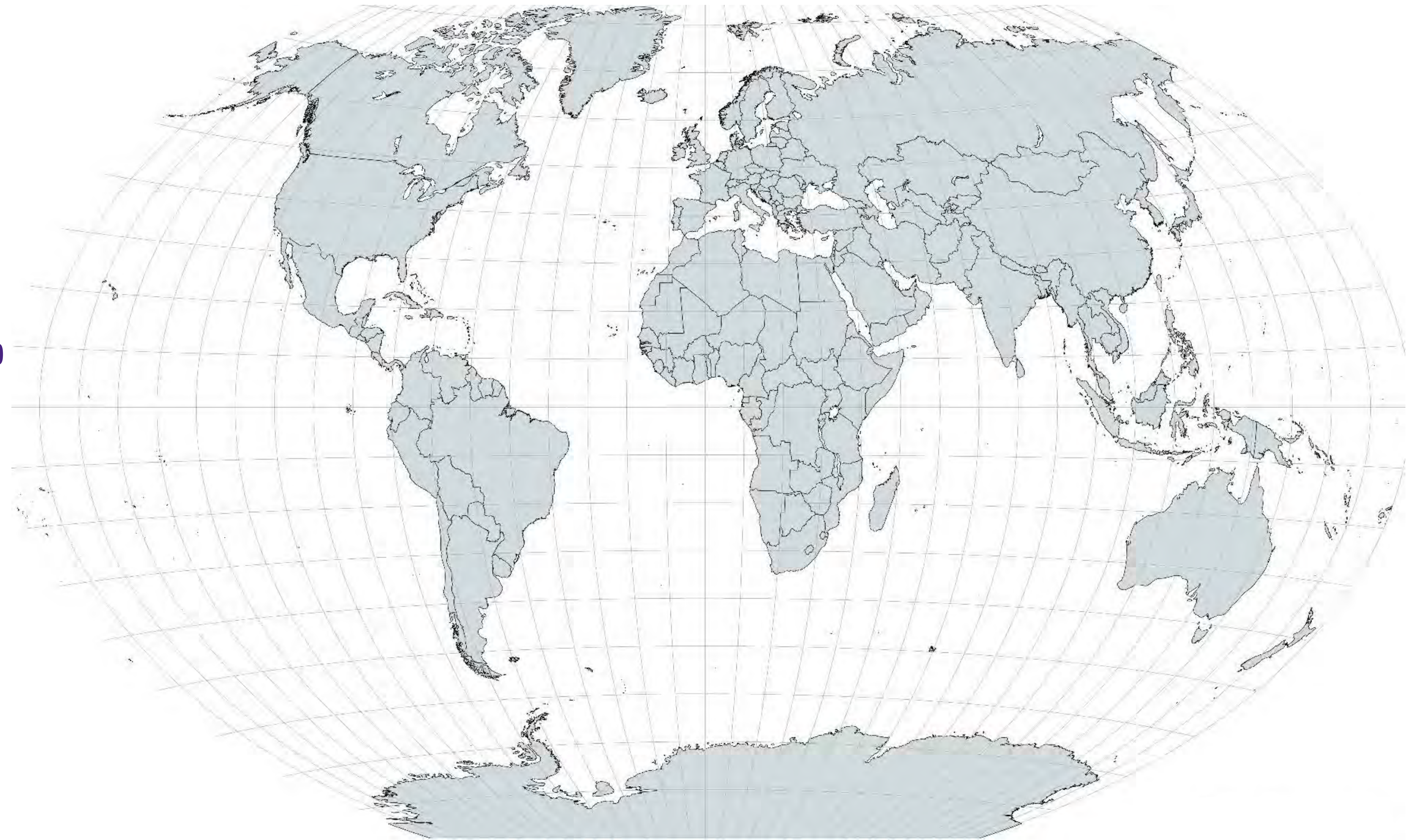
\*\* Study of first 4 months of MetaPanel test results in clinical practice in Australia



# A multi-billion dollar market opportunity

# \$25B+

Total Market Size\*



\* Assessment completed with Boston based MedTech specialist consultancy Veranex Inc. Assessment analysed US Medicare claims analysis for target patient populations, extrapolated Private and Medicaid numbers, populations and prevalence adjusted for key global markets spanning outside of US including Germany, Italy, Spain, France, United Kingdom and Australia. Pricing predicates based on approved CPT coding, reimbursed predicates, and other regional conservative pricing predicates.

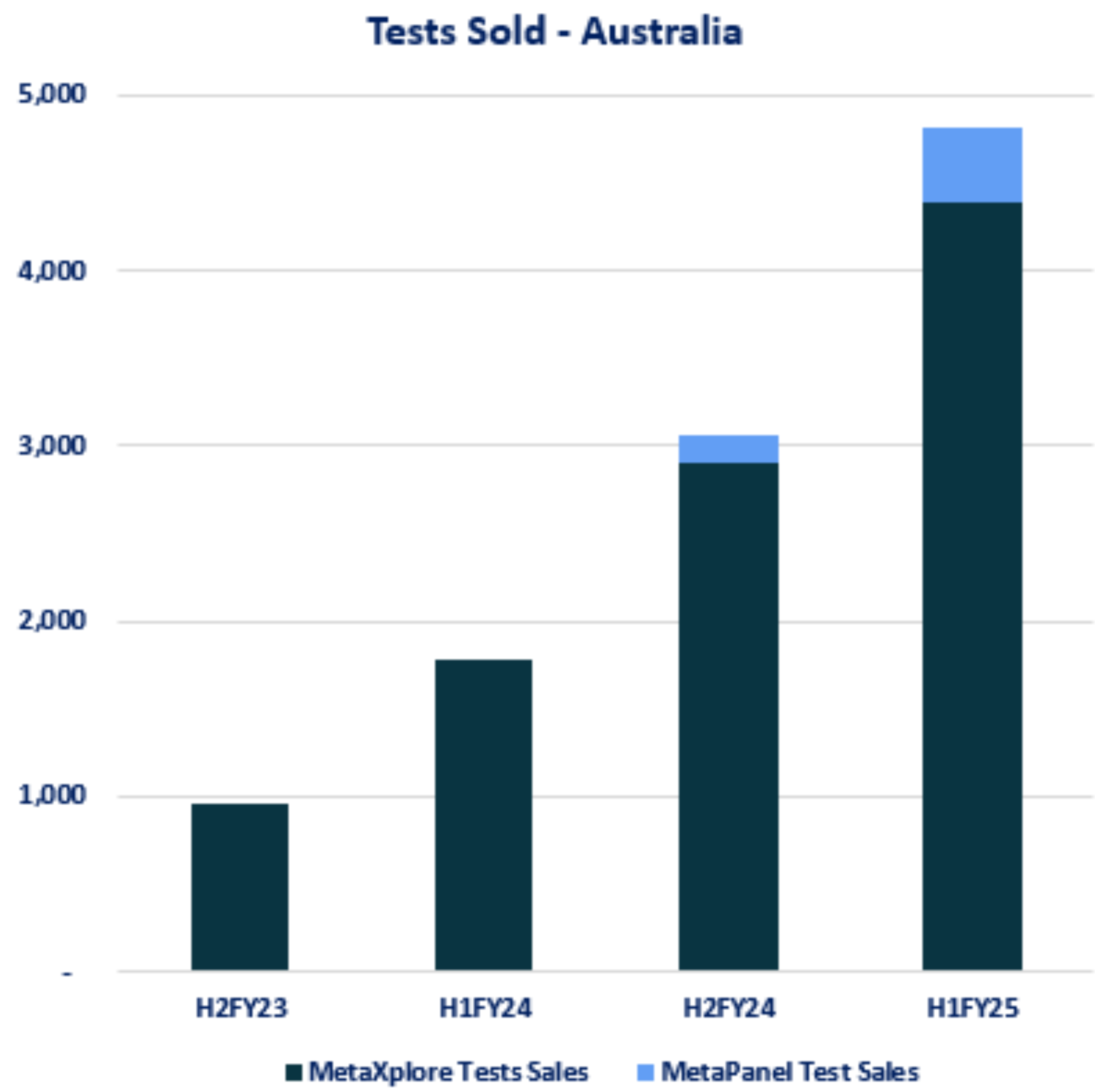


## **Our North Star Metric**

Global impact through 1 million tests



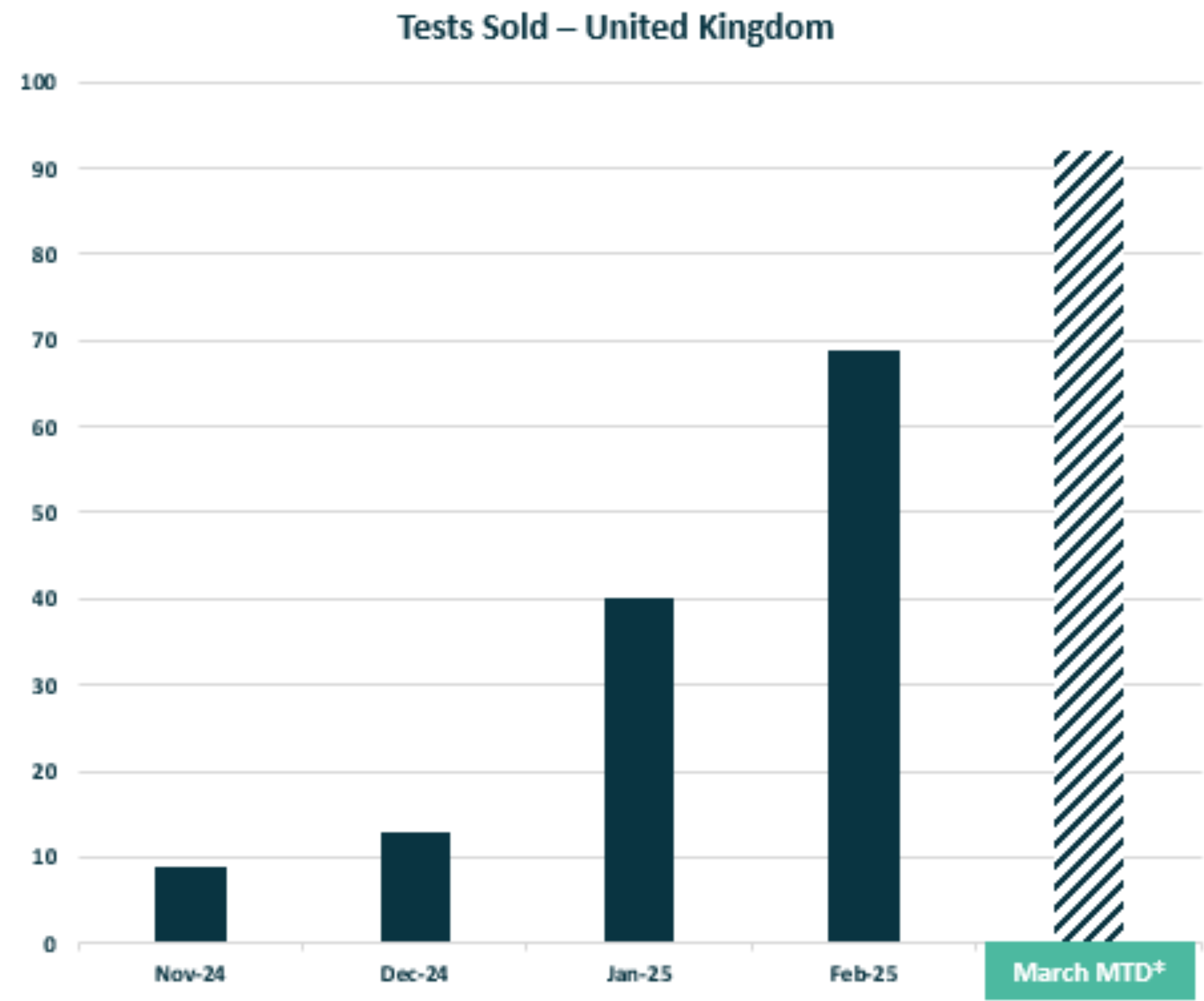
# Growing sales and clinical adoption in Australia



Australia



# Early access MetaXplore adoption in United Kingdom



United Kingdom

\*March Month-To-Date as at 19 March 2025

MetaXplore™

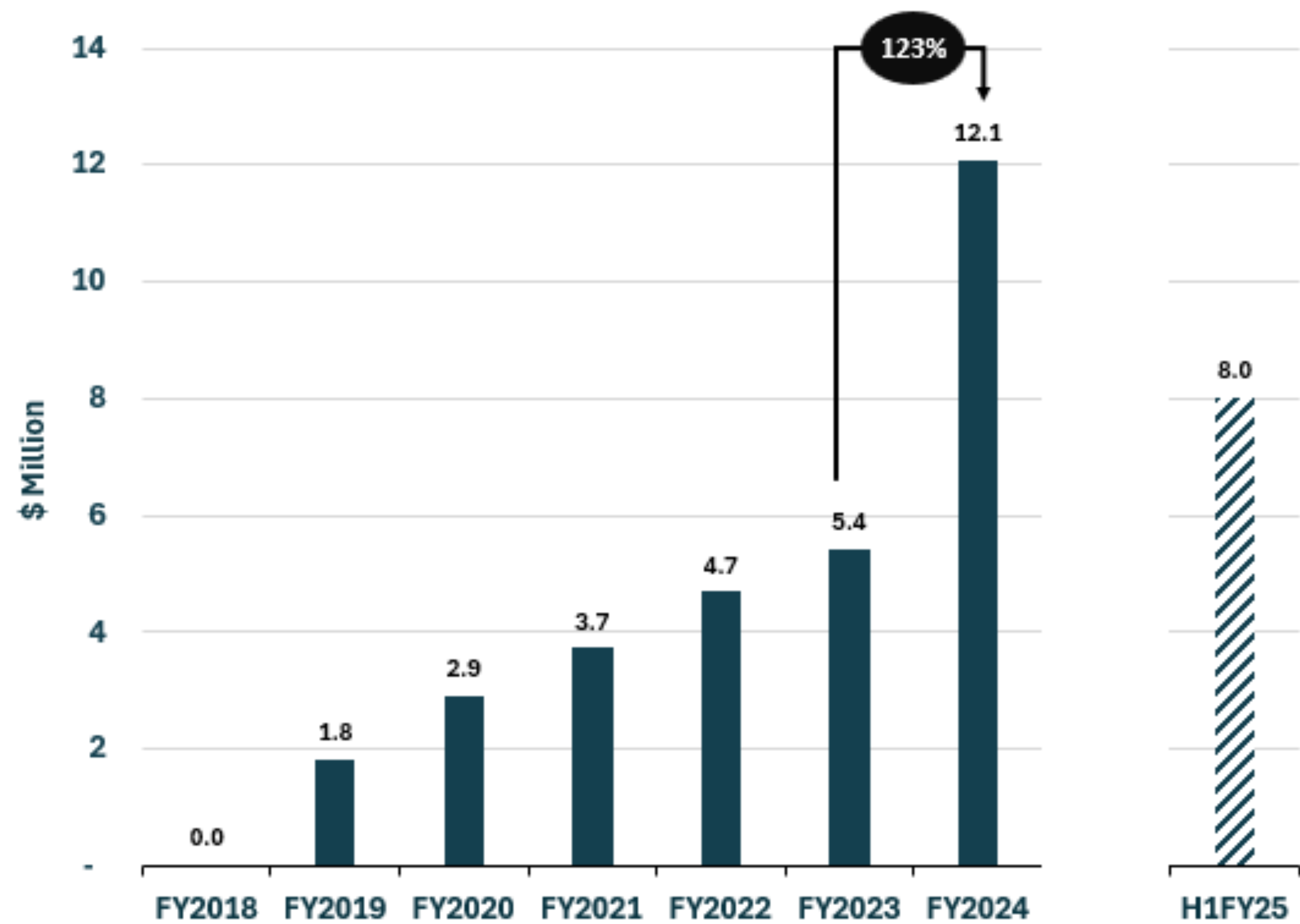


*“I have struggled with gastrointestinal symptoms for over half my life. I have tried resolving with many specialists, restrictive eating plans and natural therapies. My MetaXplore test this year identified clear problems and a personalised treatment plan. I am grateful that through following the treatment plan **I have achieved complete resolution to my symptoms and can enjoy eating unrestricted for the first time in 35 years.**”*

MetaXplore patient,  
South Australia



# Microba's annual revenue growth is accelerating





# Diagnostics Key Take Home Messages

- The market for this new diagnostic category of microbiome testing is potentially worth more than \$100B
- Our focus today is patients with unresolved GI disease, a \$25B market opportunity
- 2 world leading products addressing these patients – MetaPanel & MetaXplore
- Partnerships with two of the world's largest medical diagnostic co's - Sonic Healthcare & SYNLAB
- All driving to a north star metric of 1 million tests
- Accelerating traction in our first two markets – Australia & United Kingdom, USA to follow



SECTION 4

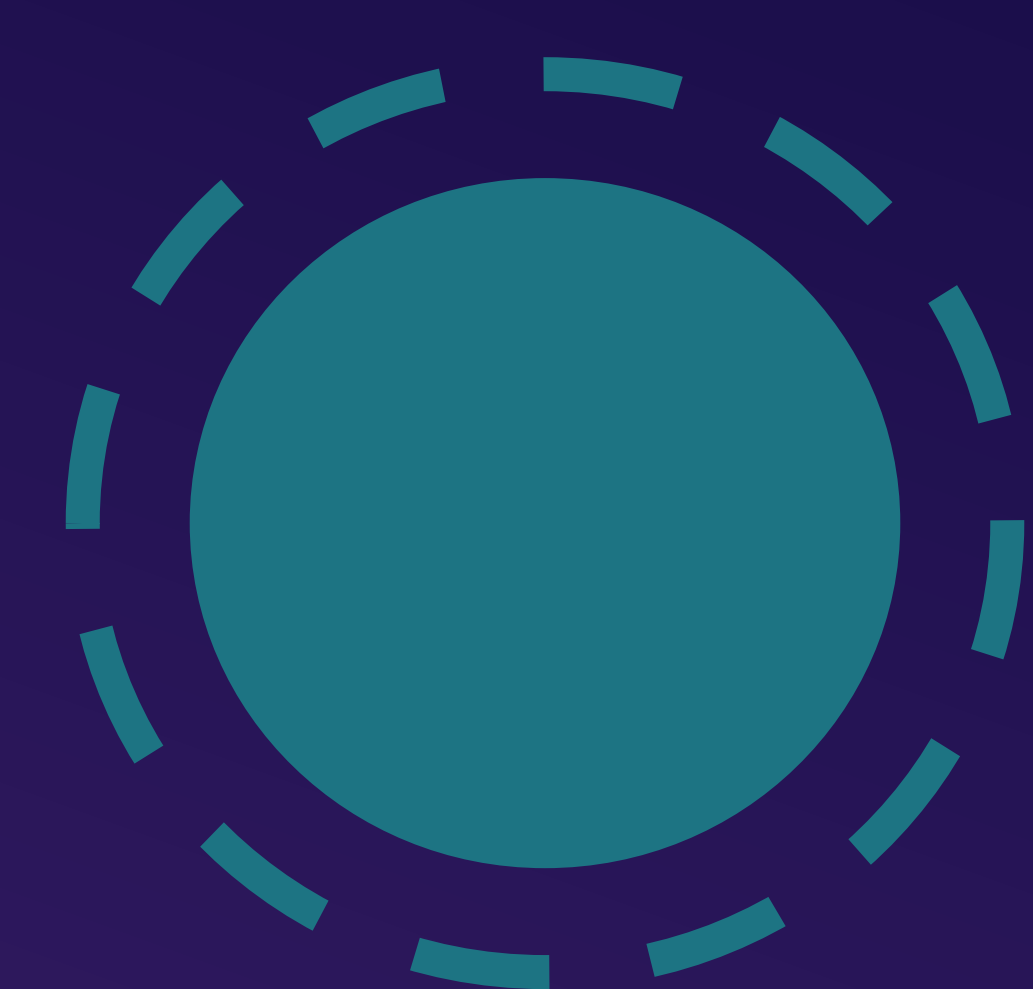
# Microba's Therapeutics

To combat disease through microbiome health

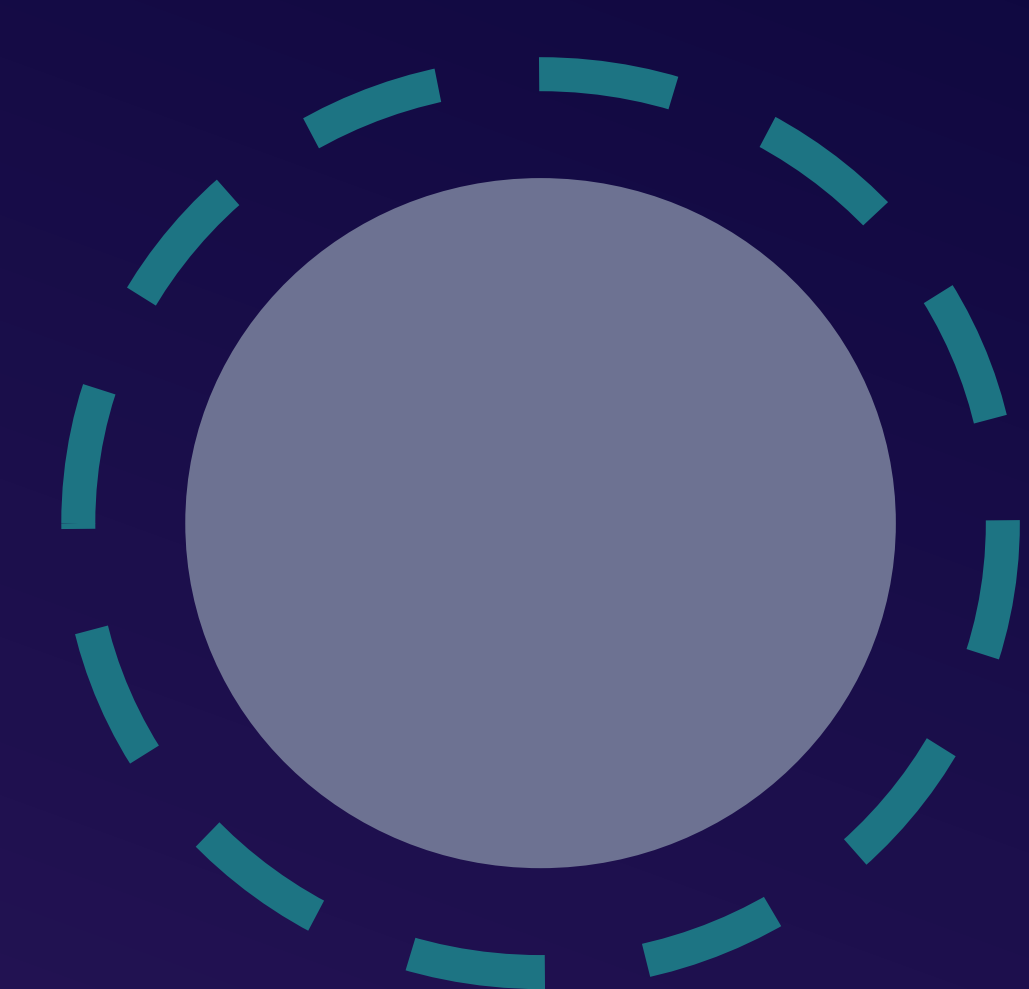


# Our primary therapeutic focus

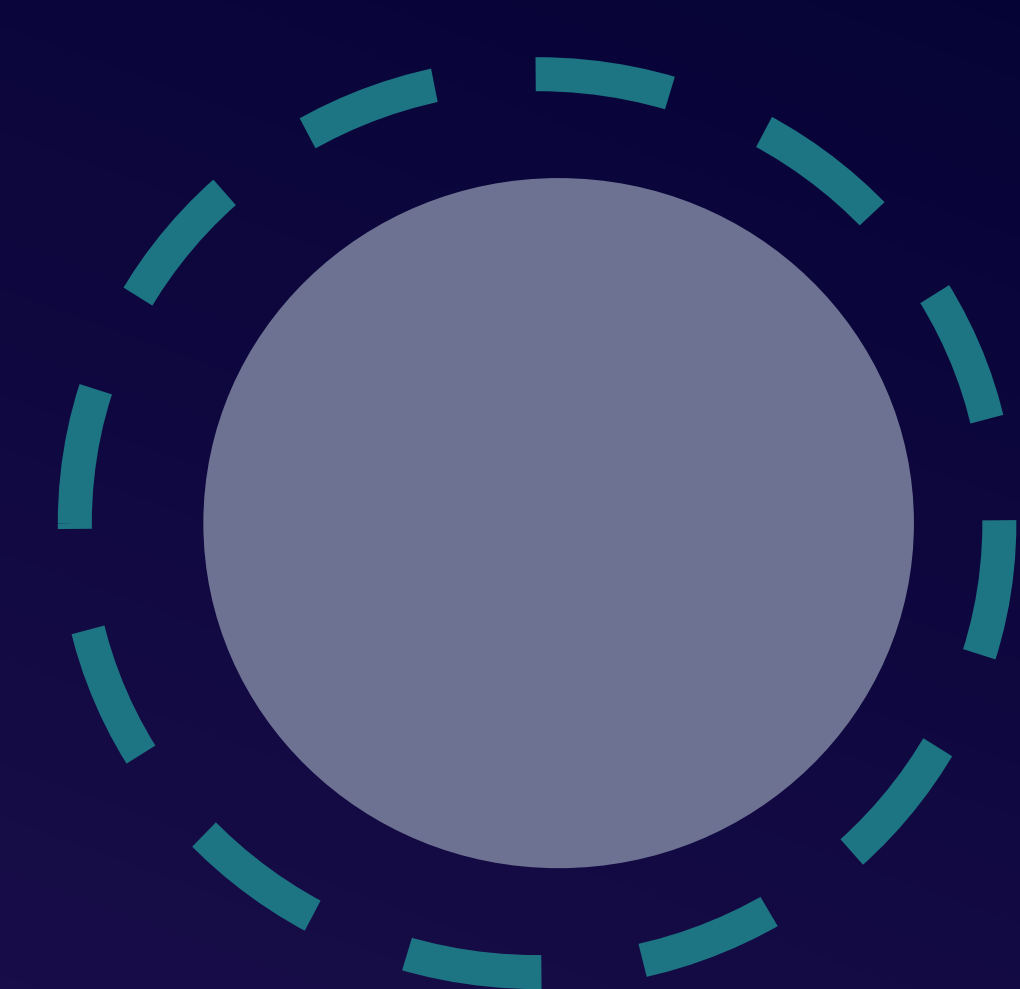
Clinical: Patients suffering from Inflammatory Bowel Disease



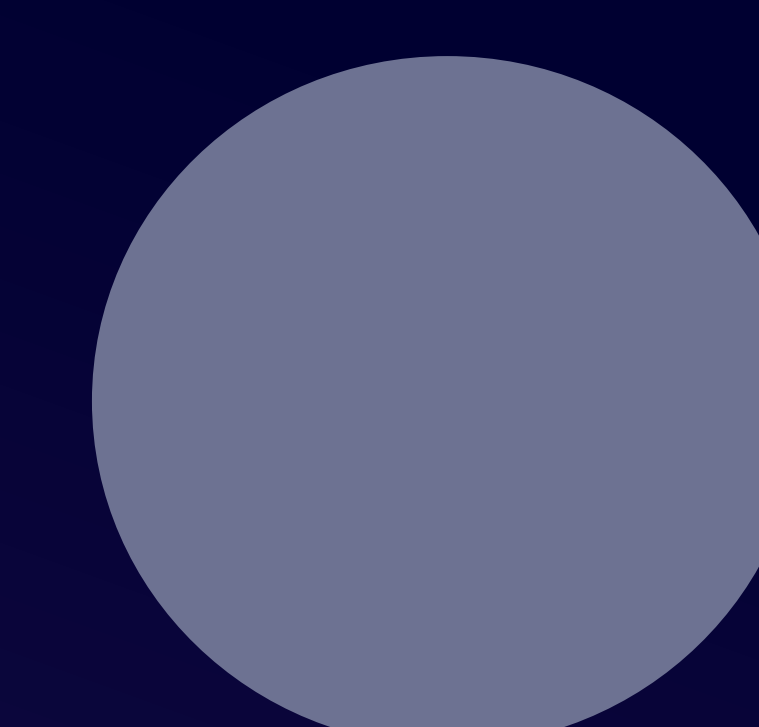
Gastrointestinal



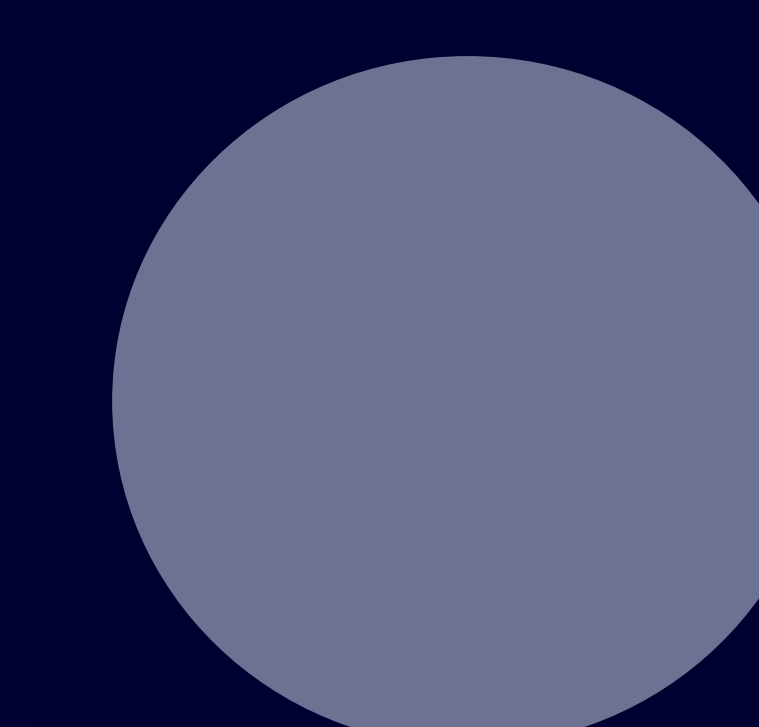
Autoimmune



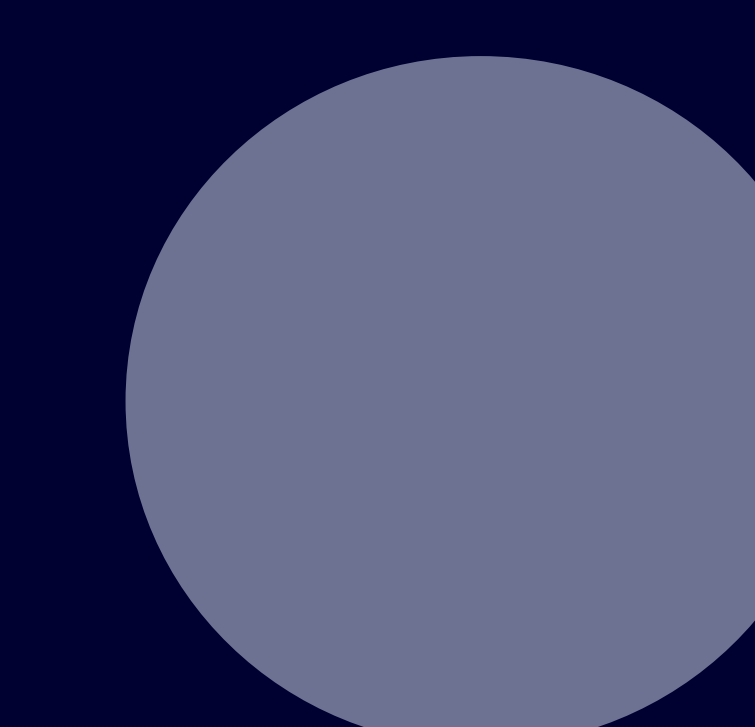
Oncology



Allergy



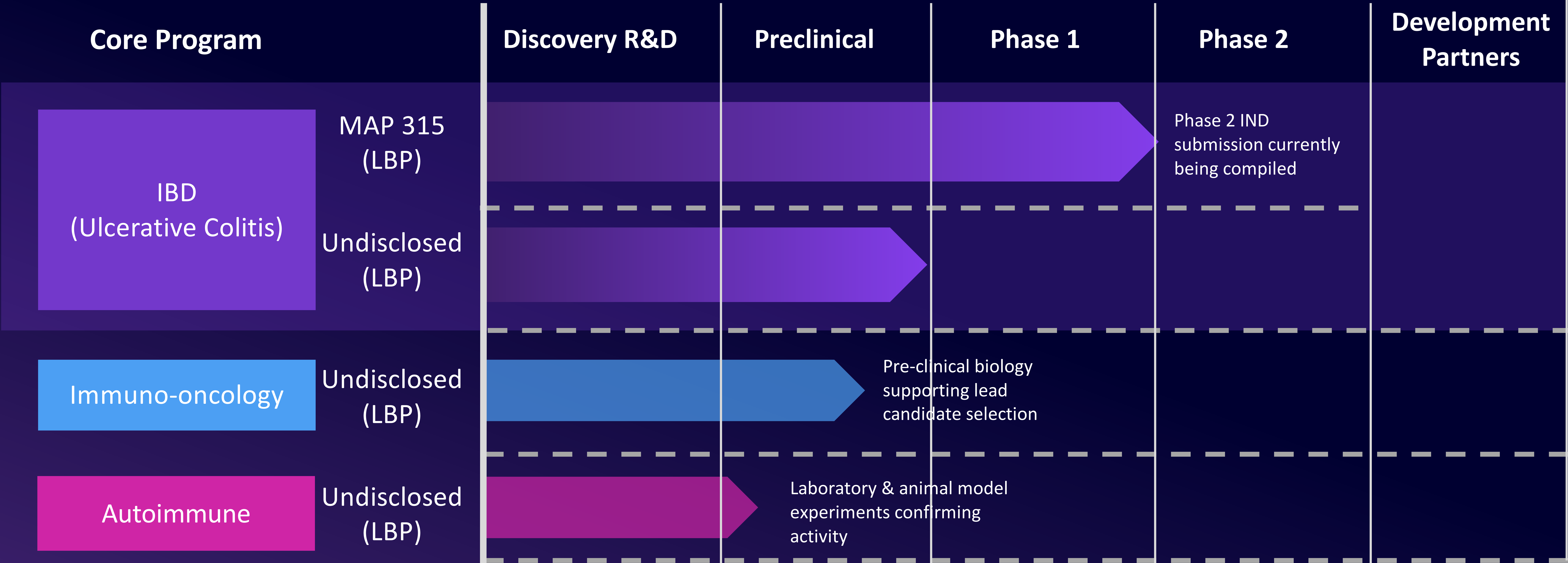
Neuro



Cardiovascular













# Therapeutic pipeline & catalysts



LBP = Live Biotherapeutic Product



# Recent IBD Transactions

Date	Deal Type	Licensee / Acquiror	Licensor / Target	Stage	Upfront	Total Deal Value
July 2024	Acquisition			Phase 2 active	-	US\$3.2B
June 2024	License			Preclinical	\$150m	US\$1.7B
October 2023	Acquisition			Phase 2 complete	-	US\$7.2B
October 2023	License			Phase 2b active	\$500m	US\$1.5B
Apr 2023	Acquisition			Phase 2A complete	-	US\$10.8B

<https://www.reuters.com/markets/deals/eli-lilly-acquire-morphic-holding-32-billion-2024-07-08/> , <https://www.reuters.com/business/healthcare-pharmaceuticals/abbvie-inks-immune-disorder-drug-licensing-deal-with-chinas-futuregen-2024-06-13/> , <https://investor.roivant.com/news-releases/news-release-details/roche-enters-definitive-agreement-acquire-telavant-including> , <https://www.sanofi.com/en/media-room/press-releases/2023/2023-10-04-05-00-00-2754288> , <https://www.merck.com/news/merck-completes-acquisition-of-prometheus-biosciences-inc/>



# Key areas of focus

## Diagnostics

- Australia – continued momentum in diagnostic sales growth and clinical adoption
- United Kingdom – accelerating MetaXplore to full market access
- United States – driving to first access and reimbursement

## Therapeutics

- Therapeutic program advancement
- Partnering and non-dilutive equity funding

Financial Snapshot	
ASX Code	MAP
Market capitalisation <sup>1</sup>	\$92m
Shares on issue	447.85m
52-week low / high <sup>1</sup>	\$0.145 / \$0.325
Cash Balance (31 Dec 2024)	\$17.3m

Major Shareholders	
Shareholder	Ownership % <sup>2</sup>
Sonic Healthcare	19.14%
Perennial	14.99%
SA Microba Holdings	7.48%
Thorney Investment Group	6.69%
Macrogen	3.98%
Philip Hugenholtz	3.84%
Gene Tyson	3.82%

<sup>1</sup> At 25 March 2025 | <sup>2</sup> At 31 December 2024





## JOIN MICROBA'S INTERACTIVE INVESTOR HUB

Visit [ir.microba.com/welcome](https://ir.microba.com/welcome) for Microba's  
interactive Investor Hub



### **Dr Luke Reid**

Chief Executive Officer  
[luke.reid@microba.com](mailto:luke.reid@microba.com)

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Woolloongabba QLD Australia





# HealthInvest

April 2025

#HealthInvest



Presenter

**PAUL ANDERSON**

CEO AND MANAGING DIRECTOR



#HealthInvest

HealthInvest April 2025





**Remplir™**

Global expansion update

April 2025







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# Orthocell at a glance

**Australian medical device company with growing international revenue and US market clearance of breakthrough nerve repair device pending**



## **BEST IN CLASS PRODUCTS APPROVED IN NINE JURISDICTIONS**

Bone / Striate+: US, EU, UK, AUS, NZ, CAN and SGP  
Nerve / Remplir: AUS, NZ and SGP



## **MANUFACTURED IN AUSTRALIA**

Scaled facility certified to manufacture in major jurisdictions under strict quality standards (i.e. MDSAP and MDR)



## **GROWING RECORD REVENUE**

Third consecutive quarter of record revenue, reporting \$2.21m in the December 24 Quarter



## **>US\$4 Billion p.a. TAM<sup>1</sup>**

Large, under penetrated markets in bone and nerve repair alone



## **STRONG BALANCE SHEET, NO DEBT, NO ROYALTIES**

Well-funded Company retaining all revenue benefits maximising cashflow



## **REMPHIR USA APPROVAL April CY25**

On track to achieve US FDA 510(K) clearance and commence sales in US\$1.6 billion market

<sup>1</sup> Addressable markets include AUS, USA, EU/UK, SGP, CAN, BRZ, JAP & THA. Referenced papers were used to estimate procedures per annum. Papers used included both US and OUS databases and studies.





# Corporate snapshot

Well-funded beyond US market clearance of Remplir, supported by leading life science institutional investors

## ASX: OCC TRADING INFORMATION

<b>Share Price</b> (as @ 26 <sup>th</sup> March)	<b>\$1.57</b>
12 month low/high	\$0.35/\$0.1.79
Shares outstanding	241M
<b>Market Capitalisation</b>	<b>~\$380M</b>
Cash (26 Mch)	~\$32M
Debt (26 Mch)	Nil
<b>Substantial Shareholders</b>	<b>%</b>
Founders & Management	~11%
Institutions & HNW's (Sankofa, Cerutti, Austral Capital, Thesis Asset Mgt, Private Portfolio Mgr's, FundBPO, Wyllie Group)	~14%

## 12 Month Share Price and Volume



~AU\$32m

STRONG BALANCE SHEET, NO DEBT, NO ROYALTIES

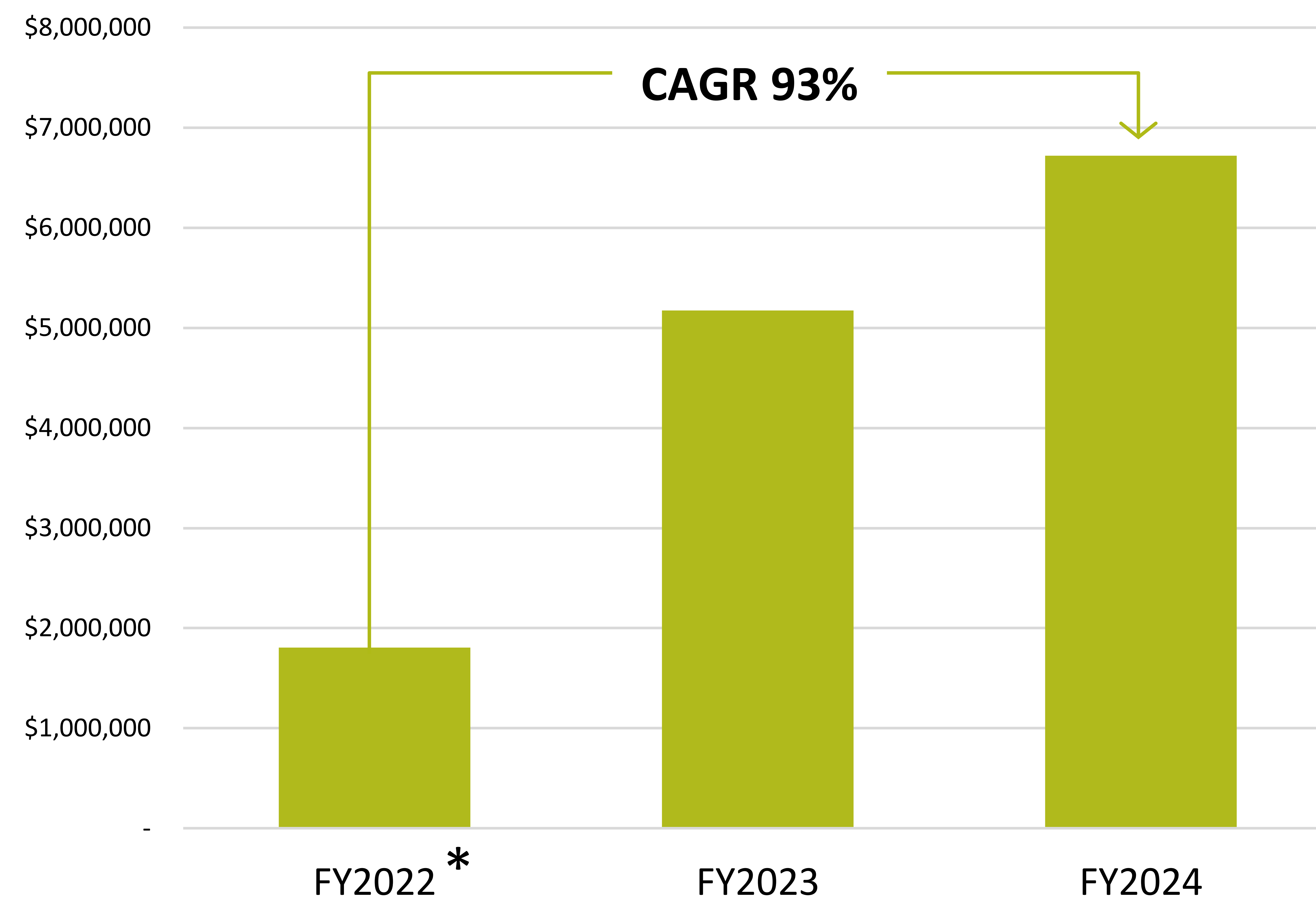




# Growing Revenue

Orthocell's rapid market penetration continues with a third consecutive quarter of record revenue of \$2.21 million reported in the December 24 Quarter.

## Total Revenue



\* US Striate and AUS Remplir sales commenced in November 2022

## Key Highlights

- **US Striate+ and AUS Remplir product sales** commenced in November 2022 and now ahead of expectations
- **Quarterly revenue has grown by 9%** compounded for the last nine quarters following the product launches in November 2022
- **Third consecutive quarter of record revenue**, reporting \$2.21m in the December 24 Quarter up 9% on the \$2.03 million achieved in the September 24 Quarter





# Highly Credentialed Board

Appointments of John Van Der Wielen and Professor Fiona Wood AM places Orthocell in a strong position to drive its products into global markets and accelerate revenue growth



**Mr John Van Der Wielen**

**Independent Non-Executive Chairman**

- 35+ years experience in international financial services including large funds management, insurance and private banking
- Former CEO of HBF with annual revenues over \$2B
- Extensive corporate strategy, institutional and strategic investor engagement and M&A transaction experience



**Mr Paul Anderson**

**Founder and Managing Director**

- 25+ years in regenerative medicine industry
- Former MD at Verigen, successfully commercialised cartilage repair cell therapy (MACI)
- Extensive experience in product development, navigating regulatory pathways, international market launches, medical education and sales force leadership



**Dr Rravi I. Thadhani**

**Independent Non-Executive Director**

- 30 years of specialist experience working in US healthcare sector - highly regarded executive, medical administrator and researcher
- Former professor of medicine at Harvard Medical School and chief academic officer at Mass General Brigham hospital, where he oversaw a \$2.3 billion research enterprise
- Extensive US regulatory experience and commercialisation of devices and therapeutics



**Professor Fiona Wood AM**

**Independent Non-Executive Director**

- 30+ years experience as a plastic and reconstructive surgeon
- Inventor of RECELL “spray on skin” treatment, now supplied by Avita Medical Inc, a AU\$450M dual-listed company with operations in 30+ countries including the US
- Unrivalled track record in development and commercialisation of innovative regenerative medicine products



**Hon Kim Beazley AC**

**Independent Non-Executive Director**

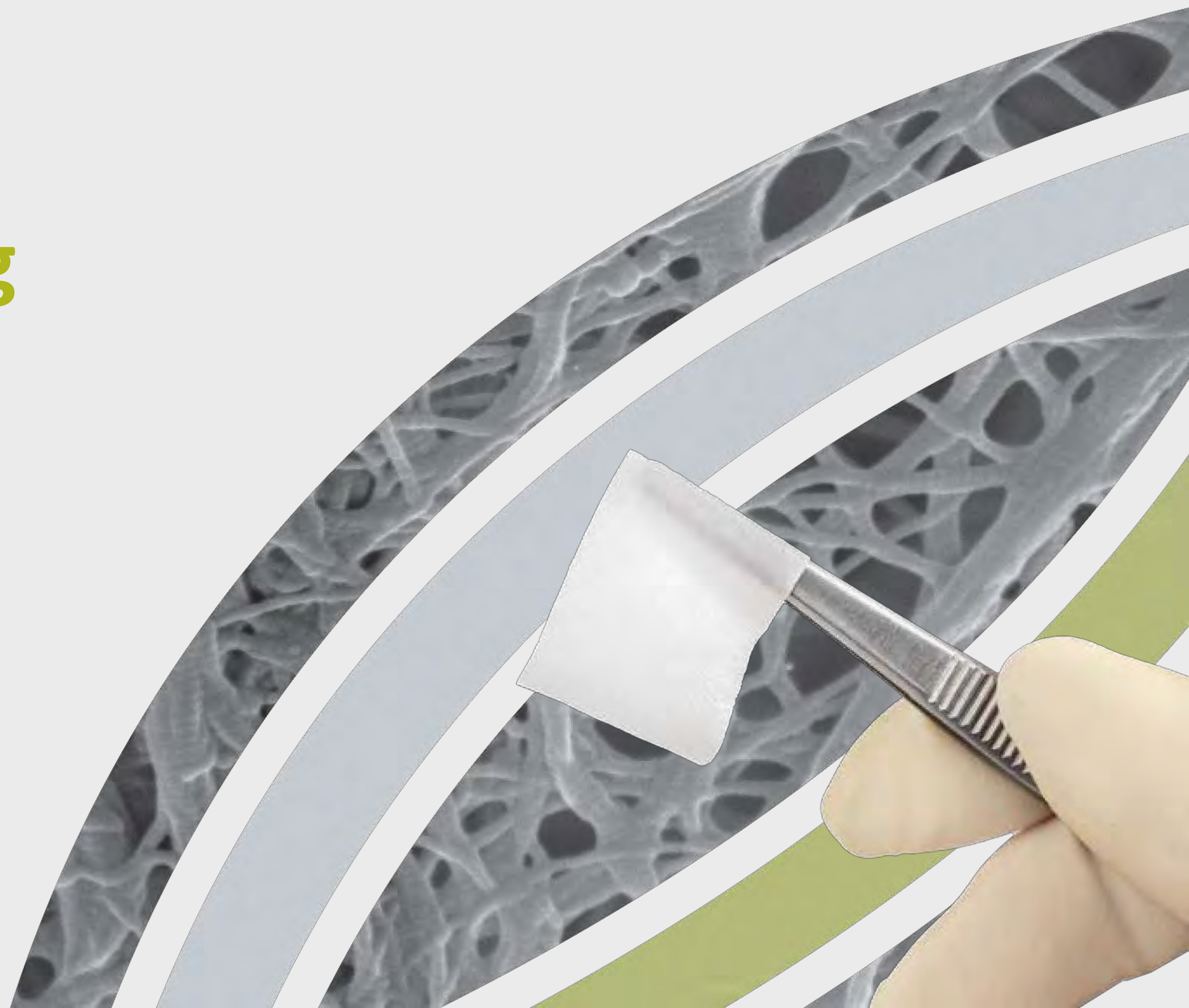
- Unrivalled experience engaging strategic partners in the US – highly regarded politician, executive and strategic adviser
- Former Australian US Ambassador and Governor of Western Australia, Deputy Prime Minister, and Minister for both Defence and Finance
- Extensive experience representing both public and private interests for Australia





# SMRT™ Manufacturing

**DEVELOPING AND MANUFACTURING  
BIOLOGICAL MEDICAL DEVICES**







# Collagen medical device platform

Our collagen medical device platform is comprised of a range of acellular, type 1 collagen devices for the surgical repair of bone, nerve, tendon and cartilage

## BONE

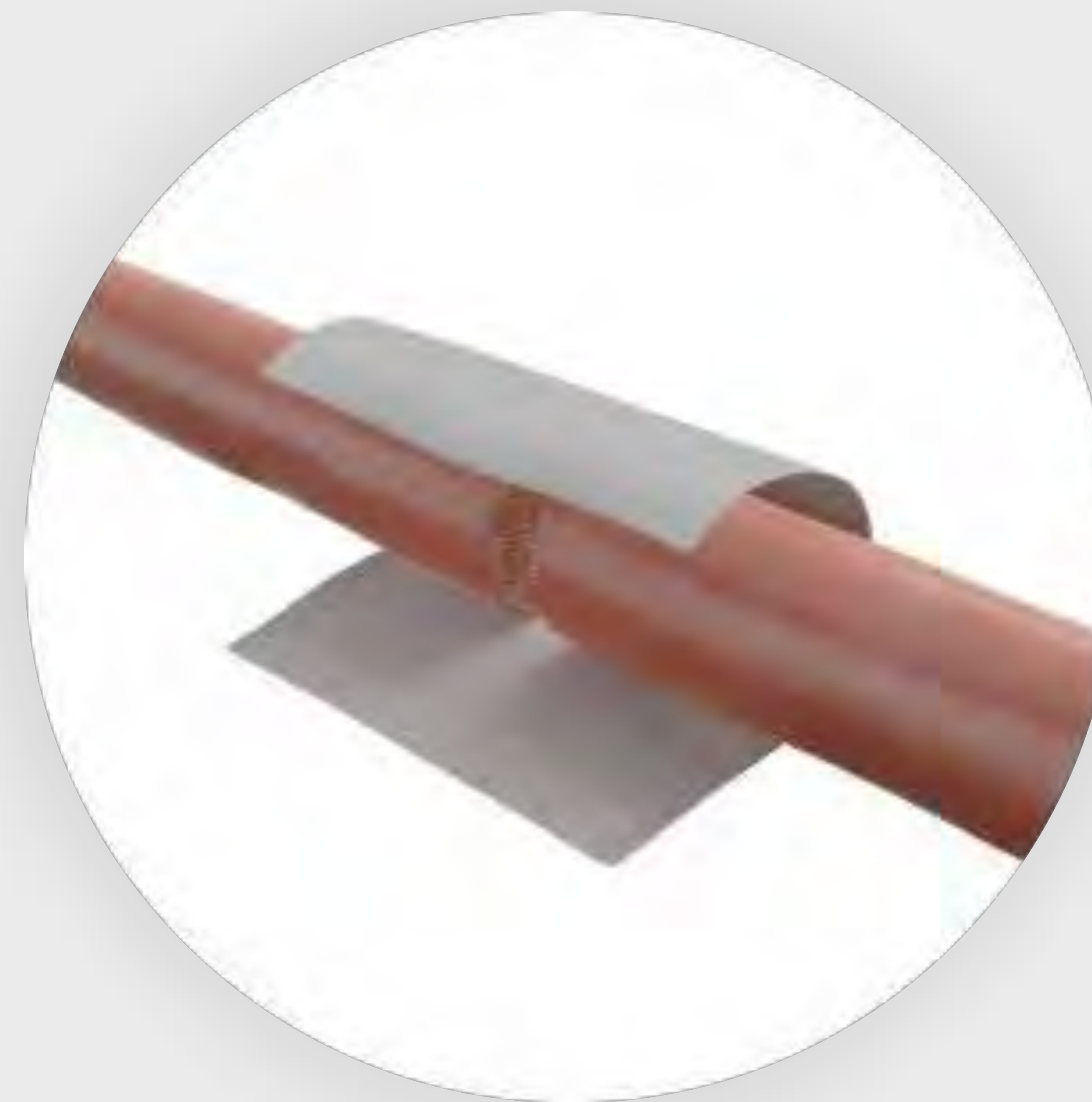
**Striate+™ membrane**  
Dental bone and tissue repair



Revenue generating in  
**US, EU/UK AU & CAN**

## NERVE

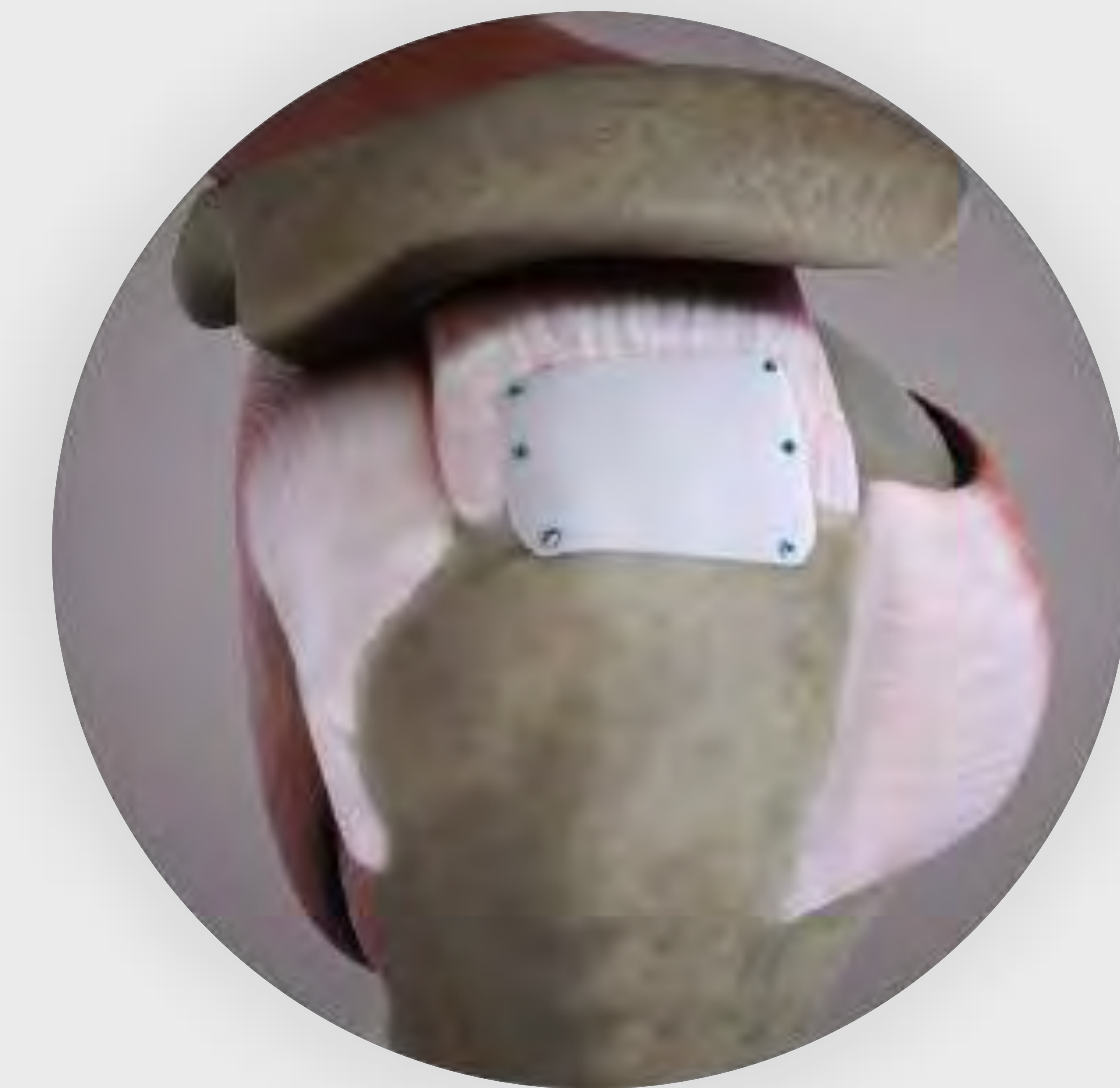
**Remplir™ nerve wrap**  
Peripheral nerve repair



Revenue generating in  
**AUS, NZ & SG**

## TENDON

**SmrtGraft™ scaffold**  
Tendon repair



AUS launch  
**CY 2025**



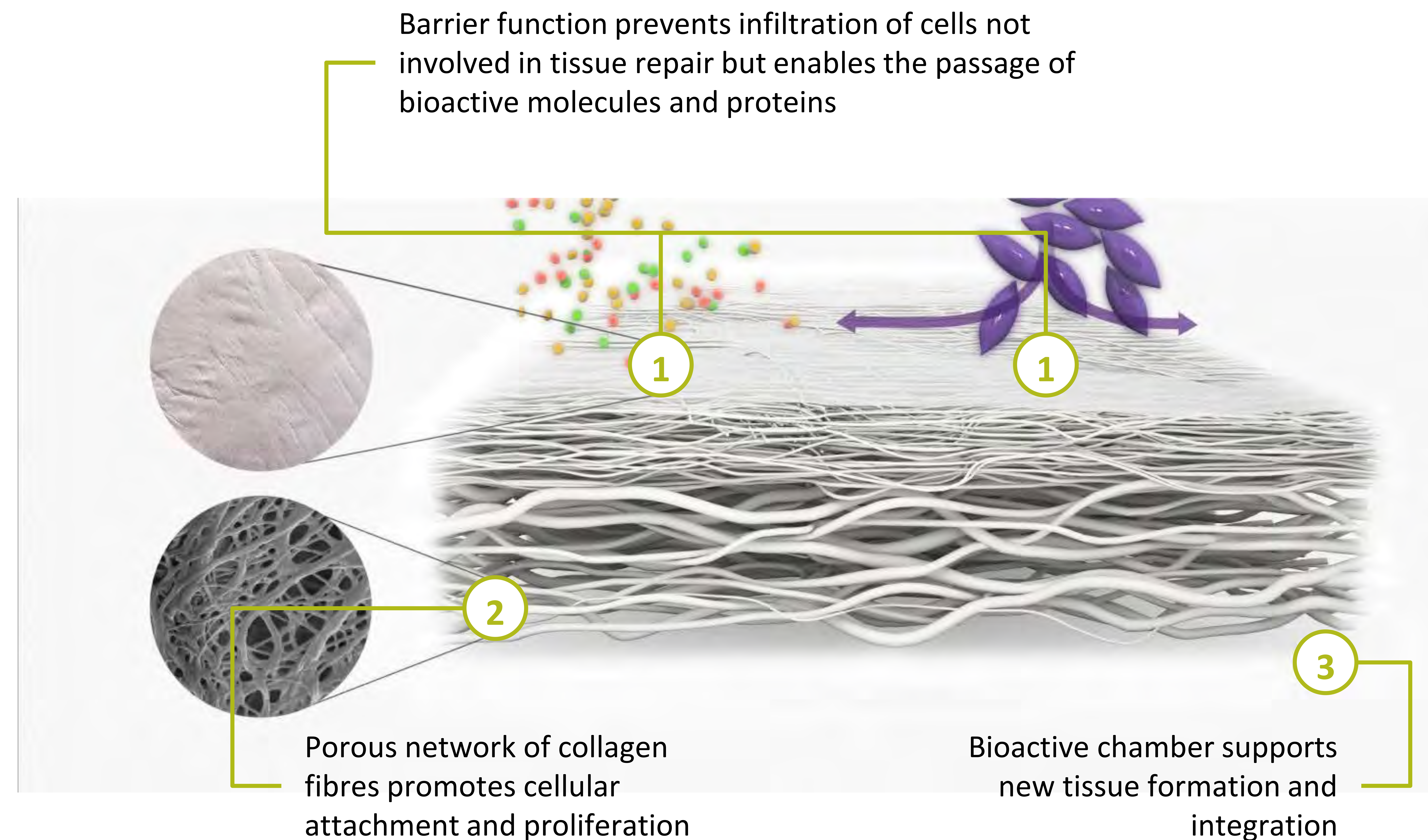


# SMRT™ manufacturing

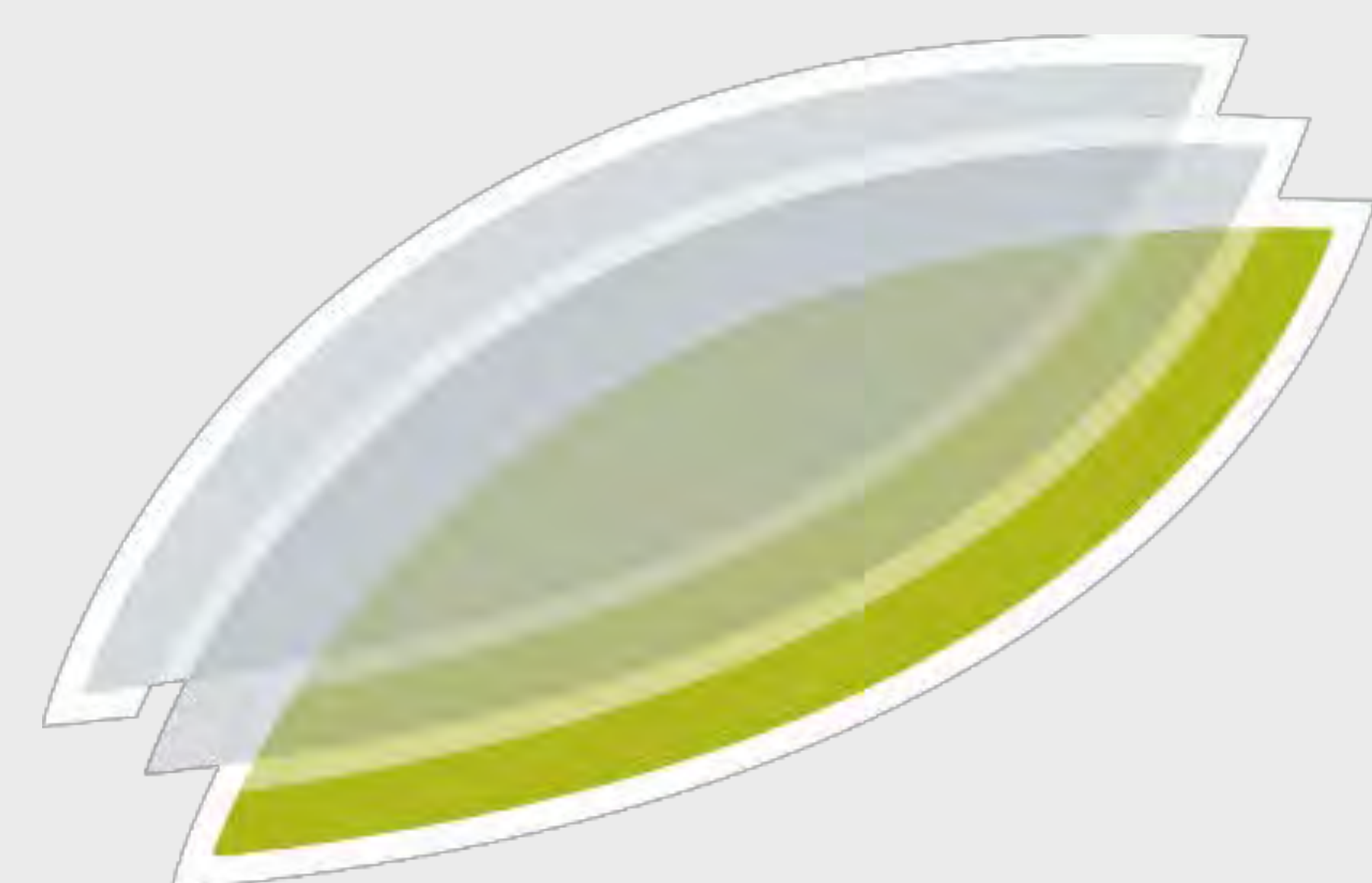
Orthocell develops and manufactures innovative collagen medical devices that deliver the highest quality surgical repair of bone, nerve, tendon and cartilage

## SMRT manufacturing process

- **Pure collagen**  
Decellularization process removes all cellular and genetic material
- **Mimic human collagen**  
Natural collagen structure is preserved creating the ideal environment for cellular attachment and proliferation
- **No immunogenic reaction**  
**70,000+ implants globally**  
Devices integrate and degrade commensurate with the tissue healing process







**Remplir™**

**REDEFINING NERVE REPAIR**

ortho·cell



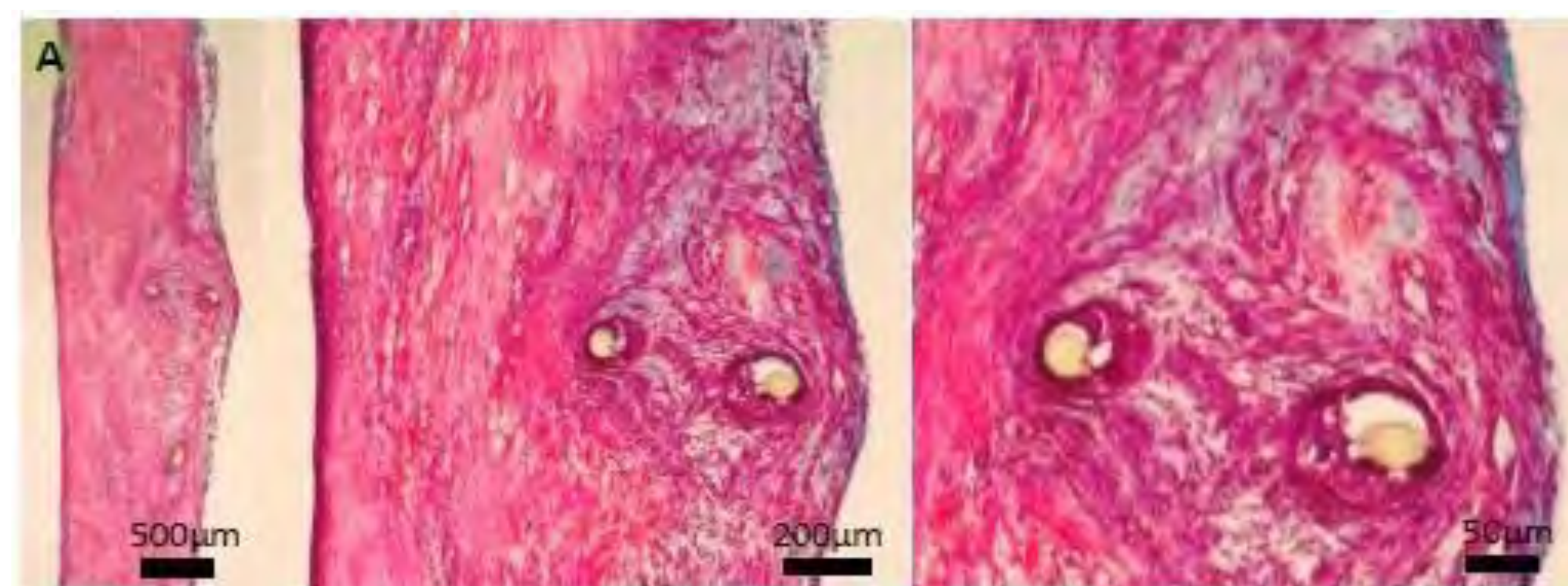
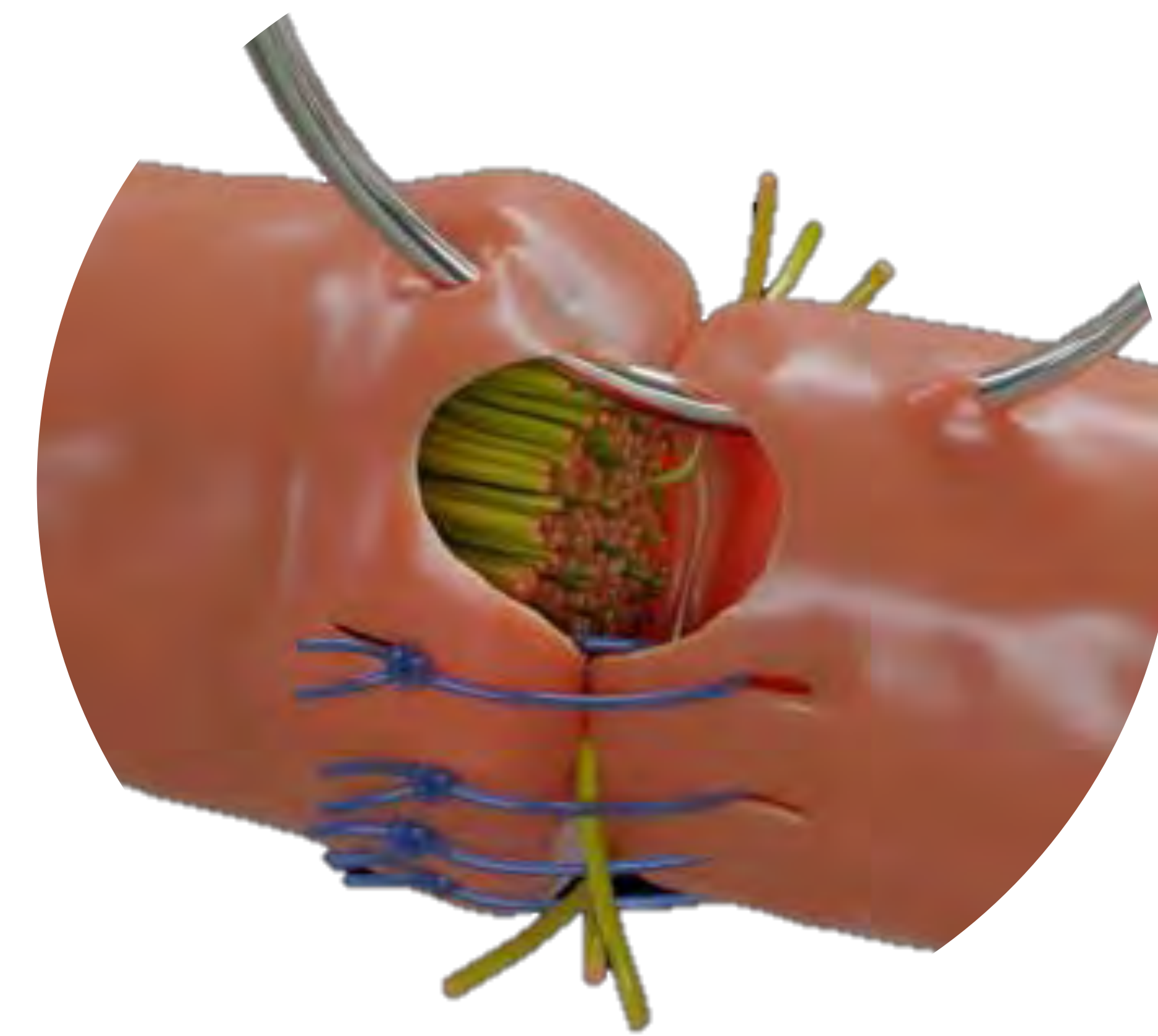




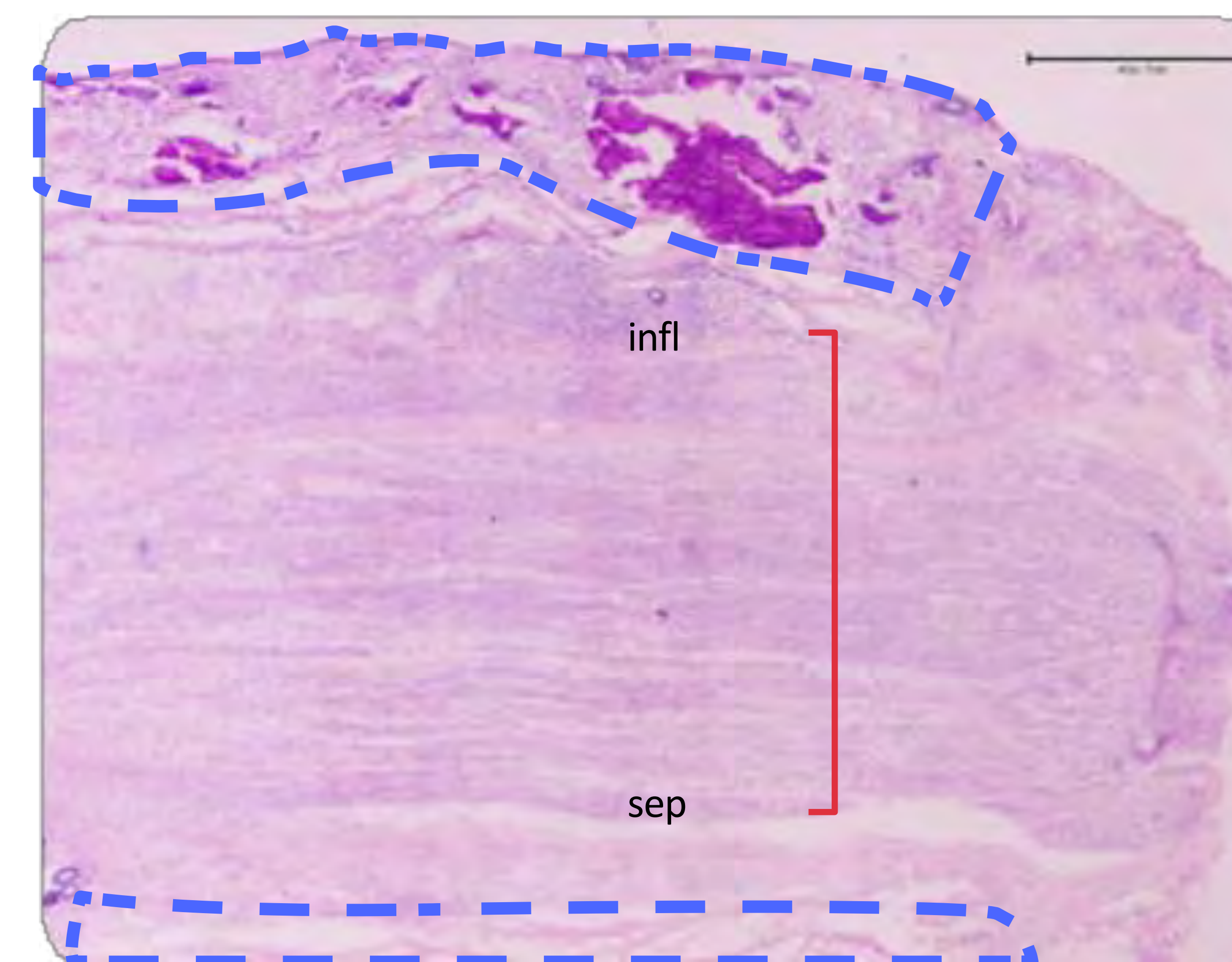
# Remplir™: Nerve repair breakthrough

Current repair methods can place delicate nerve tissue under tension, causing scarring, fibrosis and neuroma formation

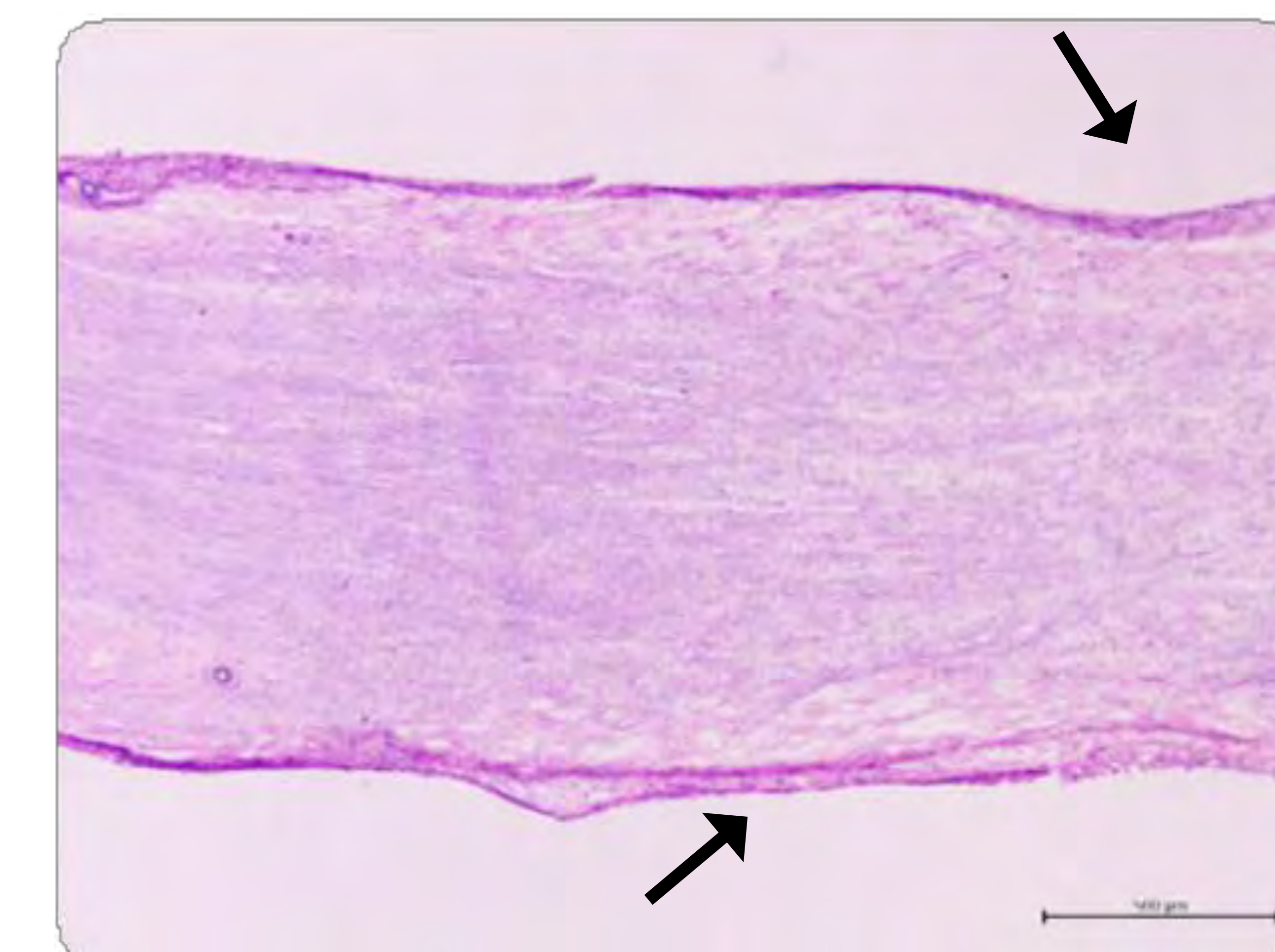
**1860s**  
**Suturing**



**2000s**  
**Conduits**



**2020s**  
**Next generation**



**Remplir™**

**Success  
Rates**

**50-70%**

**55%**

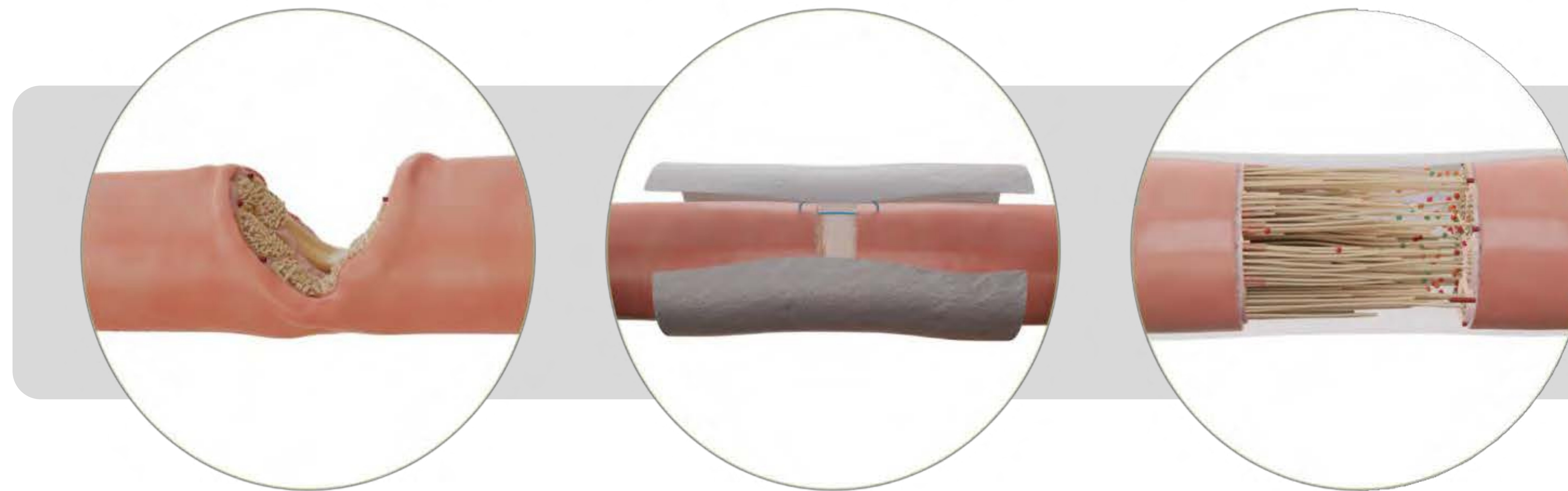
**85%**





# Remplir™: Redefining nerve repair

Collagen nerve wrap approved and reimbursed in Australia.  
Intended for use in peripheral nerve repair



GUIDING PREDICTABLE  
OUTCOMES IN  
PERIPHERAL  
NERVE REPAIR

- ✓ Exceptional handling characteristics
- ✓ Reducing sutures
- ✓ Mimics epineurium (nerve outer layer)
- ✓ Returns nerve to pre-injured state

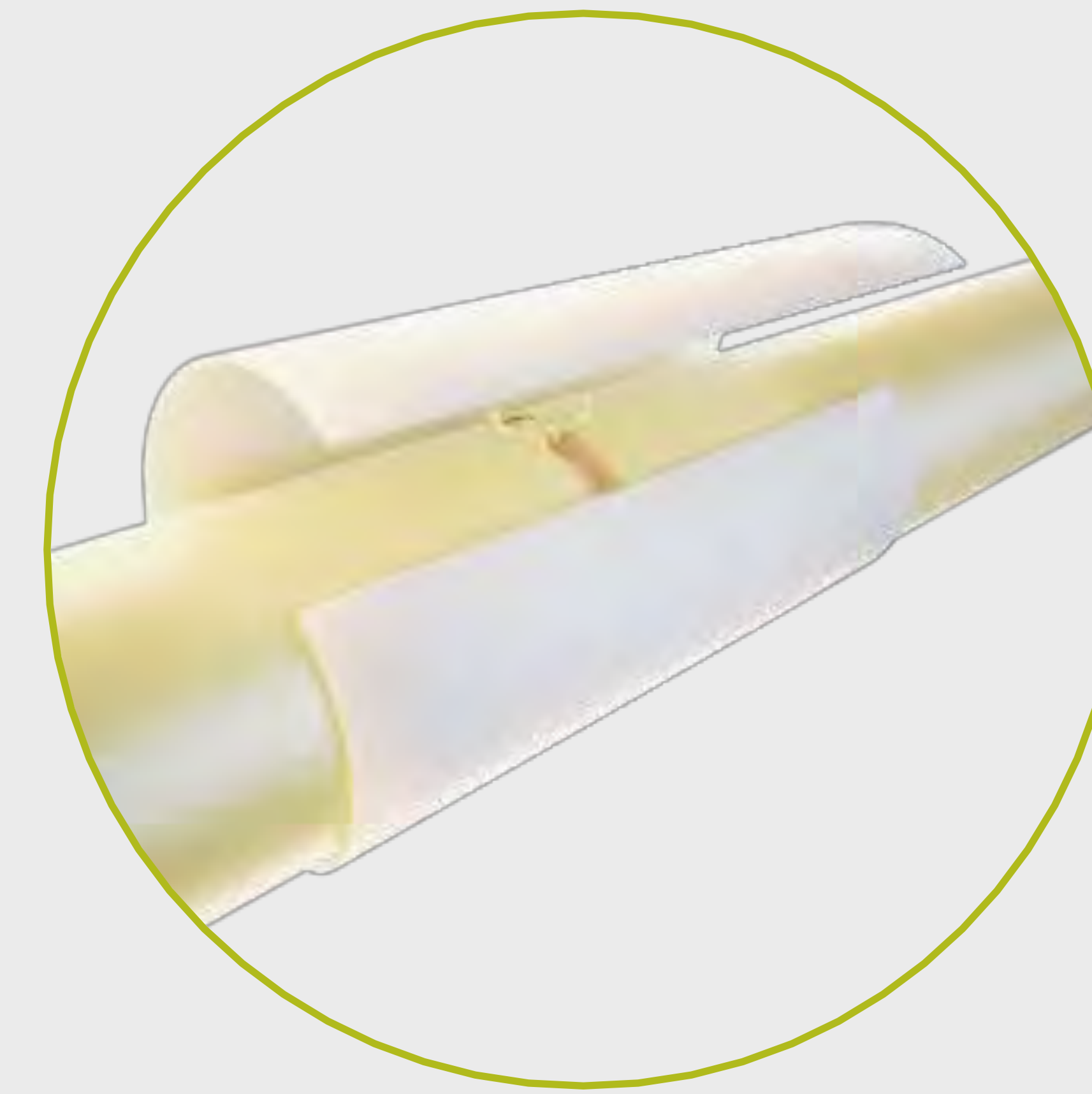






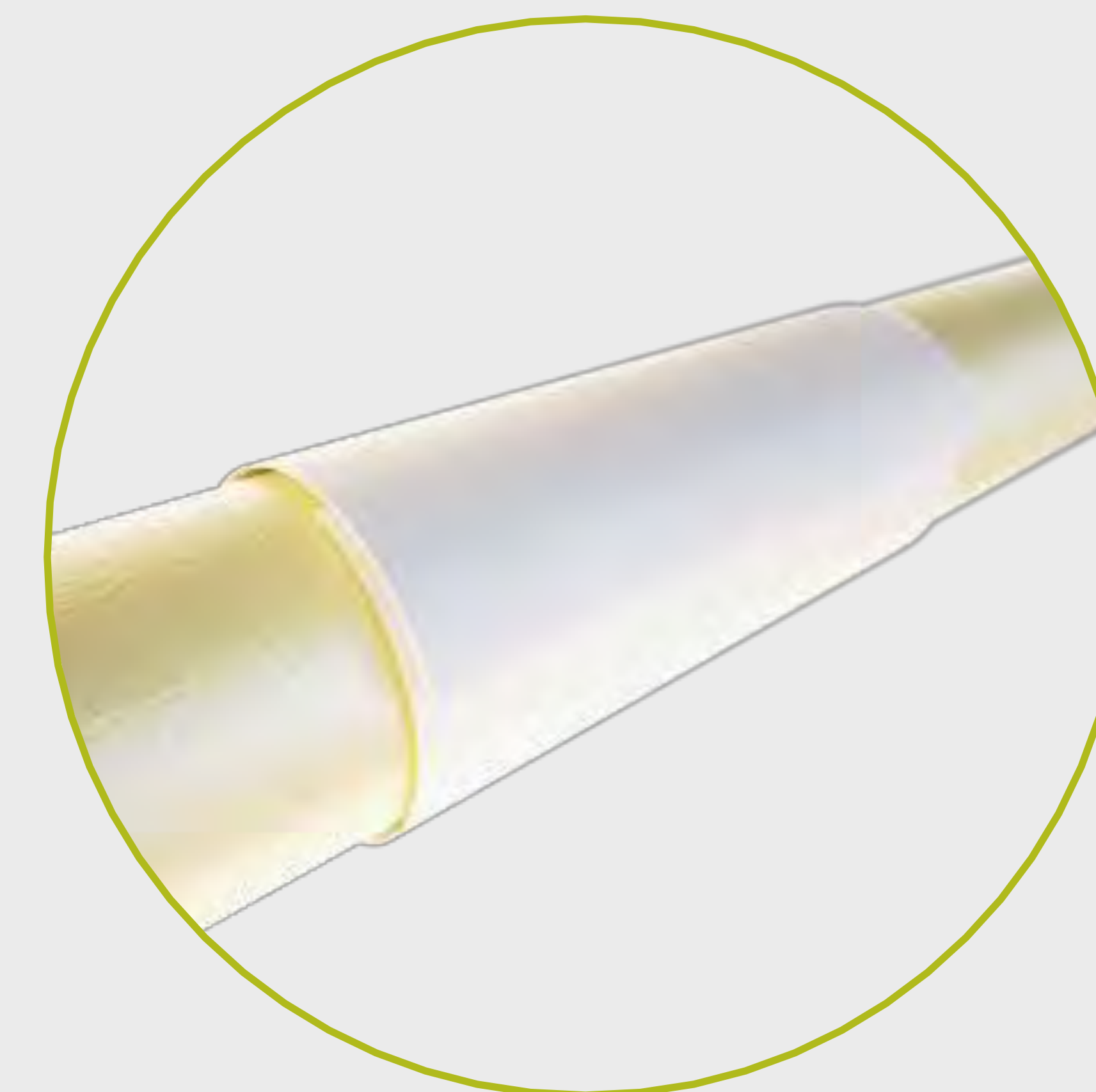
# Remplir™: indications

Remplir is the only device that can be used for either connecting severed nerves, protecting damaged nerves or capping amputated nerves



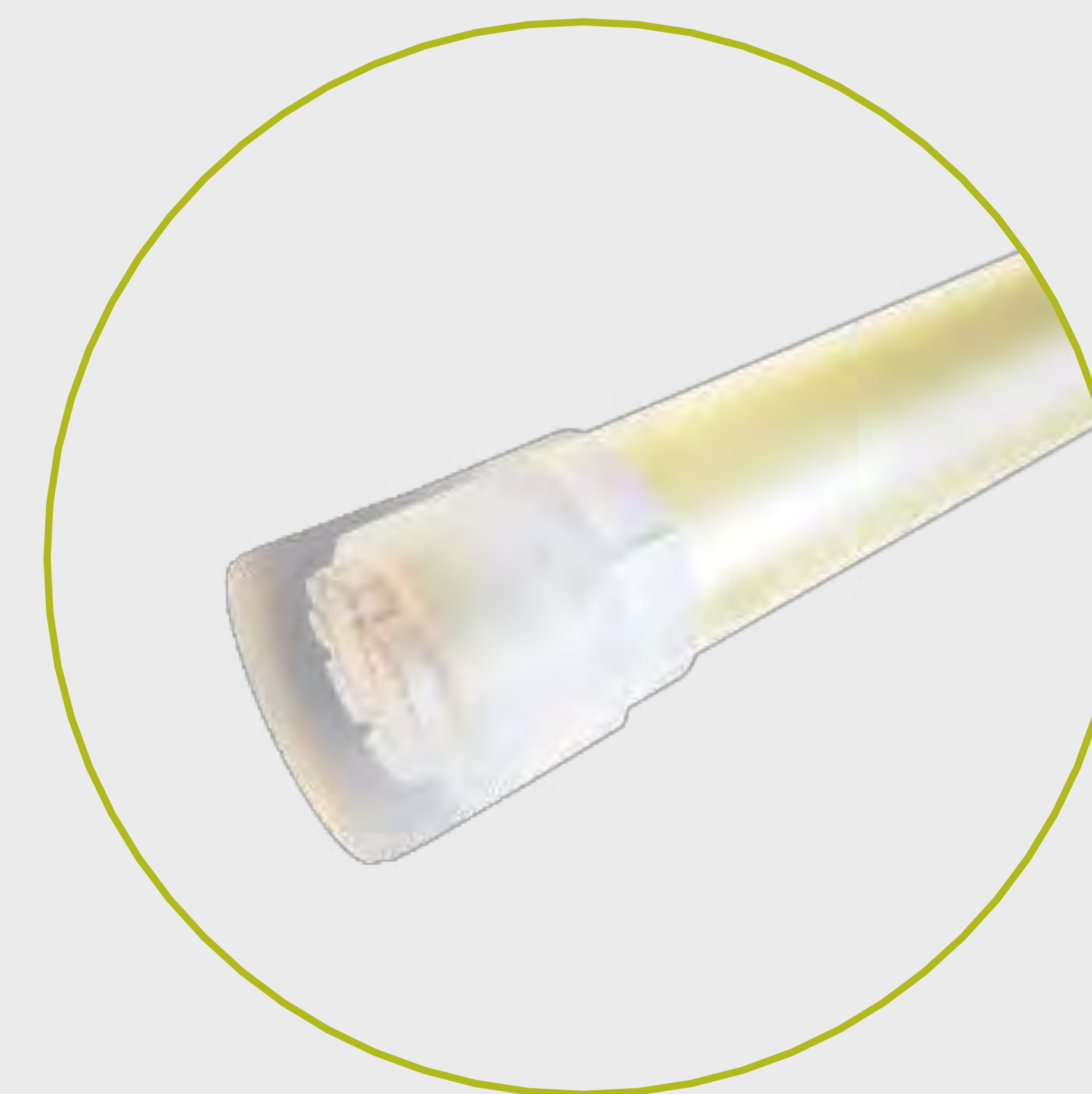
## CONNECT

Trauma: motor vehicle, power tool, surgical injuries, sports and military related accidents



## PROTECT

Compression: blunt trauma, revisions surgeries (e.g. carpal/cubital tunnel)



## CAP

Amputation: amputations, stump neuroma, mastectomies, schwannoma





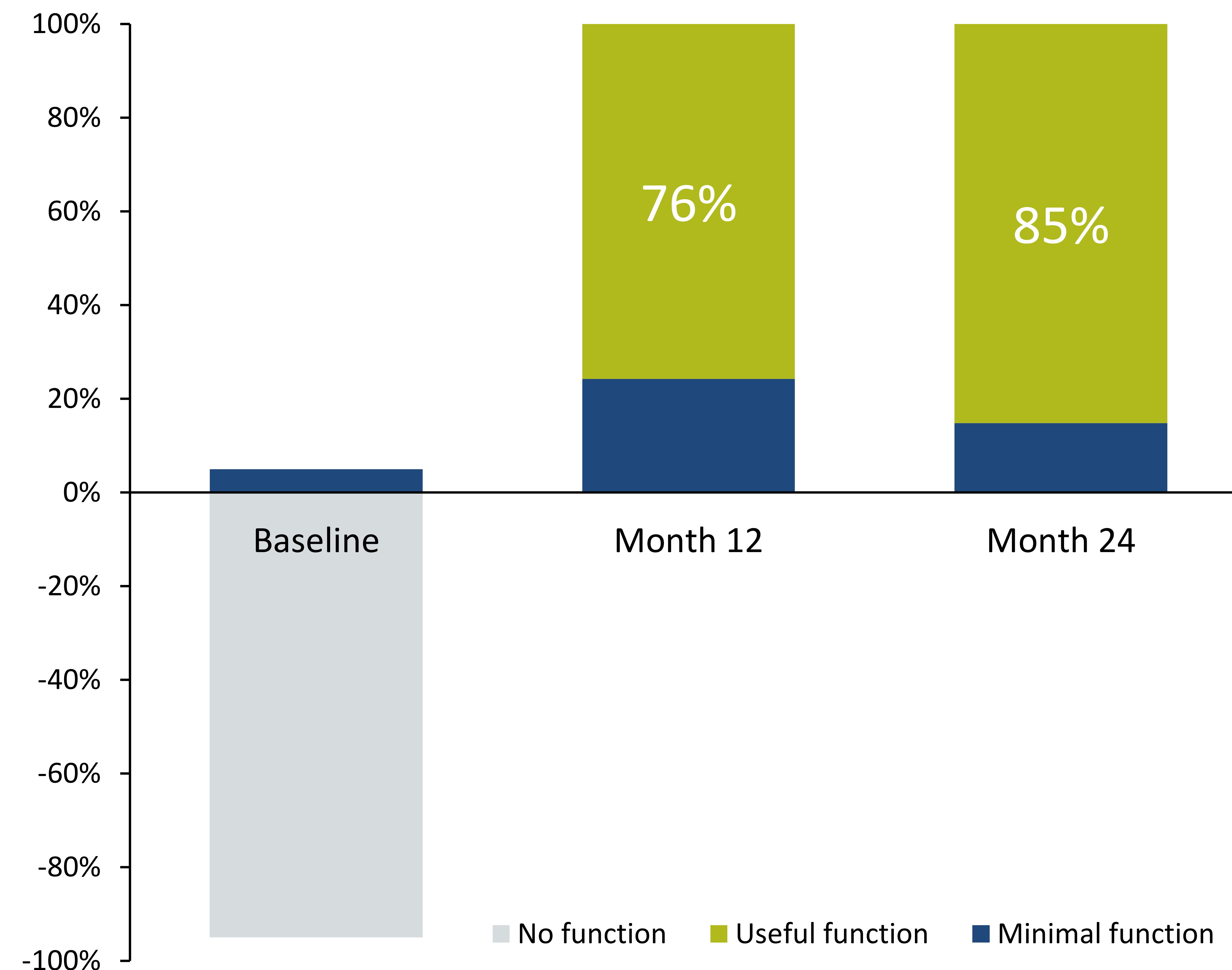
# Remplir™: compelling clinical results

Patients regained voluntary muscle movement within 12 months,  
increasing strength and range of motion at 24 months



We are now seeing a consistent return of arm and hand function following nerve transfer surgery with Remplir. Remplir is increasing the success rate and efficiency of nerve transfer surgery.

- Leading Australian orthopaedic nerve specialist and clinical trial lead, Dr Alex O'Beirne



## Useful Function

Voluntary movement with improved strength and range of motion

## Minimal Function

Voluntary movement restored, limited strength and range of movement

## No Function

No voluntary movement

## FINAL RESULTS

**85% (23 of 27)** of nerve repairs resulted in functional recovery of muscles controlled by the repaired nerve





# Australian Remplir™ case study opens up global nerve repair opportunity

## Injury

- Mountain bike accident
- C5 quadriplegia

## Impact

- No arm strength and no movement in fingers and thumbs
- Life in a wheelchair was difficult

## Surgery

- Nerve transfer using Remplir™

## Outcome

- Better fine motor control and can do things with two hands
- Playing wheelchair rugby and driving his car



Remplir™ patient:  
Adrian Walsh

This treatment has made a world of difference to me.  
The increased strength and mobility in my arm and  
hand has really boosted my independence.  
I am contributing more around the home and can help  
my wife and kids – it feels good.

- Adrian Walsh, Remplir™ patient



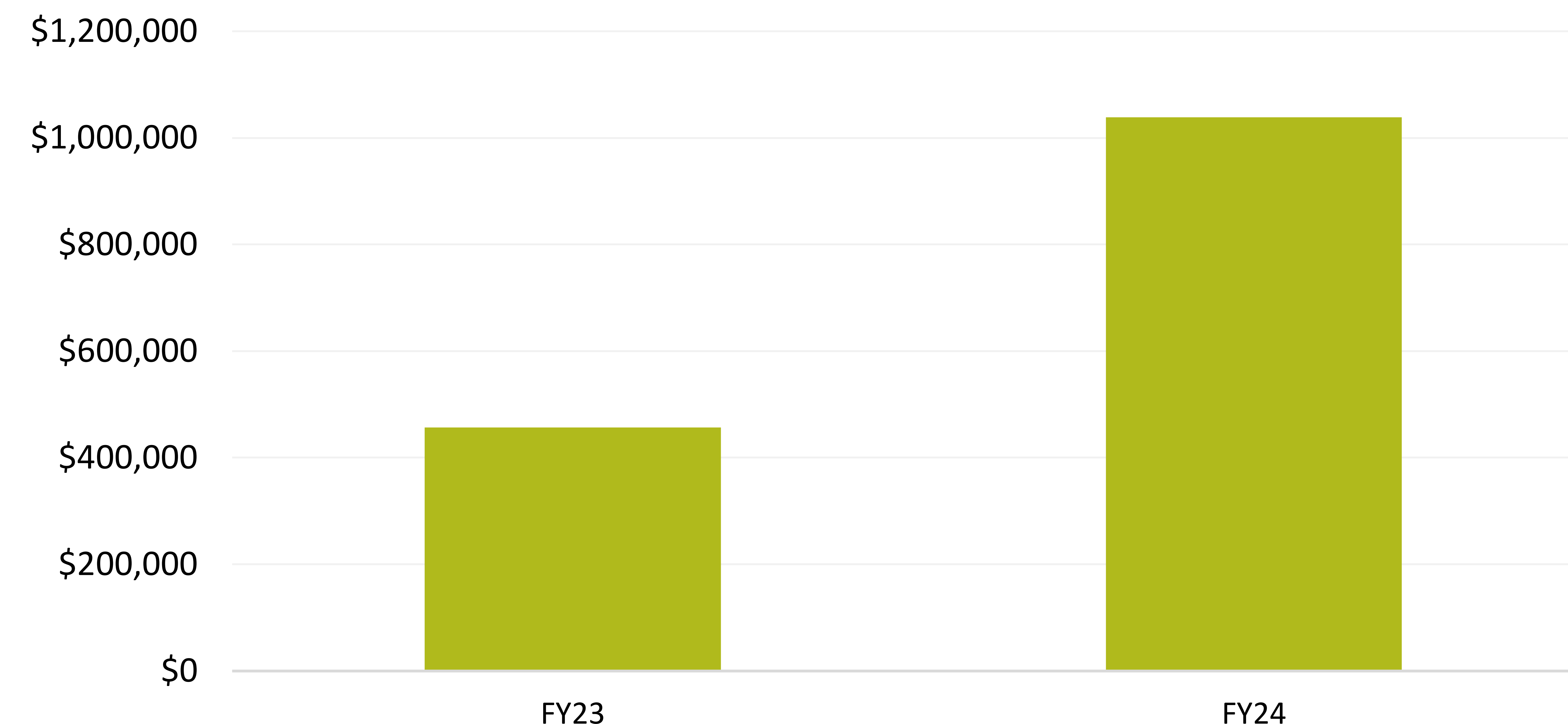




# Successful launch with growing revenue

AUS commercial launch<sup>1</sup> of Remplir with Device Technologies, reimbursed in the private healthcare system in November 2022, with sales unit volumes exceeding expectations

## Remplir product revenue since AUS market launch



- **127% growth in Remplir revenue from \$457K in FY23 to \$1.04M in FY24**
- **Product sales to Device Technology significantly exceeding guidance** – over 180 orthopaedic and plastic reconstructive surgeons
- **First major international regulatory approval** - appointment of an exclusive distributor and achievement of first sales in the key market of Singapore
- **Adoption drivers** - enables less suturing, creation of the optimal healing microenvironment and facilitation of free gliding within the repair site during the critical healing period

1. Orthocell supplies Device Technologies (DVT) with Remplir products, and DVT exclusively market and distribute Remplir in Australia.





# US FDA APPROVAL EXPECTED MARCH / APRIL CY25 TO US\$1.6 BILLION MARKET

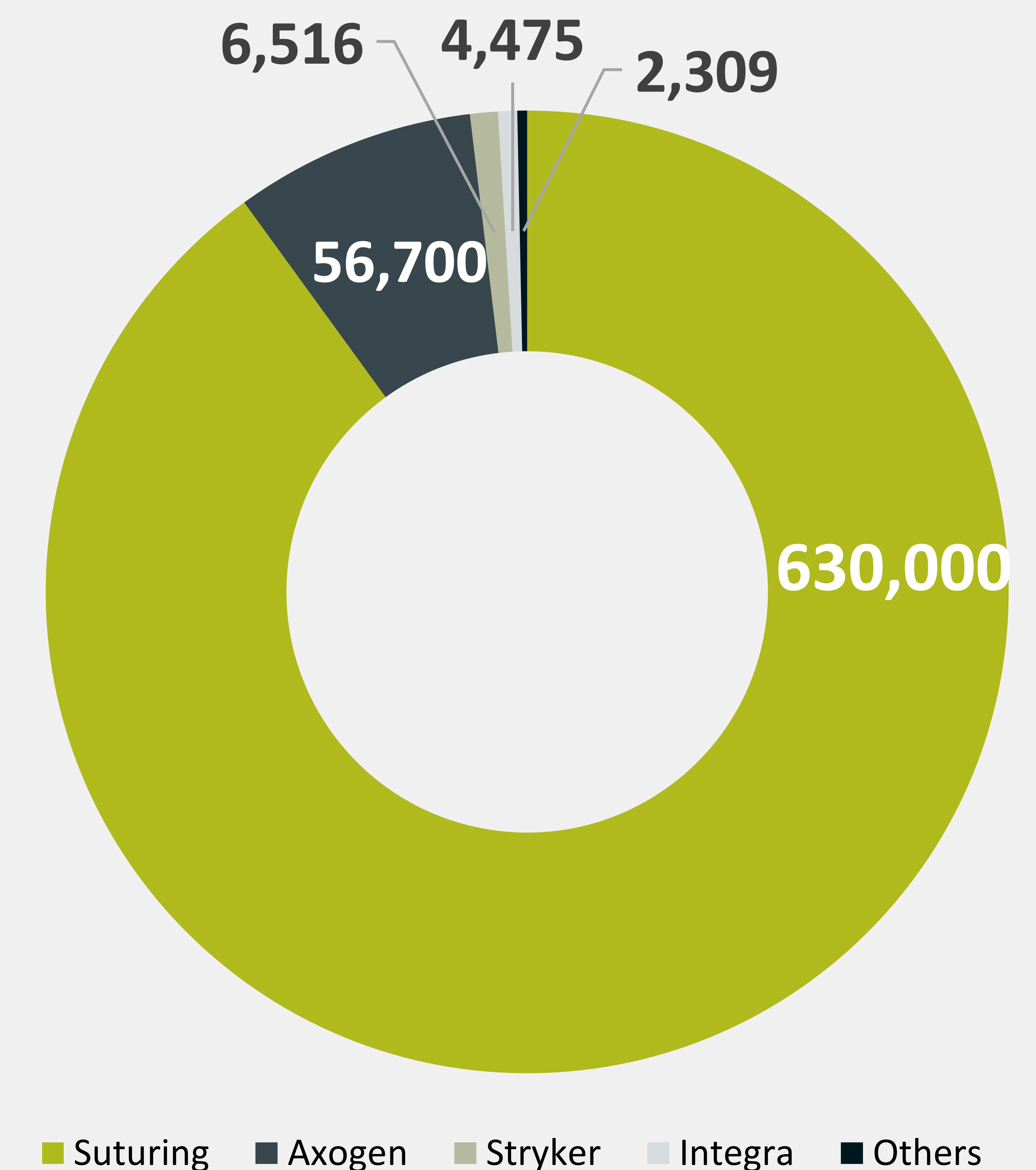


Over 700,000<sup>1</sup> peripheral nerve repair procedures in the US per year, 90% undertaken using suture only method.

- **Successfully completed the 510(k) Regulatory study**, meeting all endpoints and providing key data required to support December 24 marketing submission
- **US market clearance anticipated in April 2025** immediately followed by sales
- **Current devices are not widely adopted** due to suboptimal outcomes – Axogen, Integra and Stryker collectively sell ~70k units per year (10% of procedures)

1. Referenced papers used to estimate peripheral nerve procedures in the US per annum. Papers used included both US and OUS databases and studies

## Annual US nerve reconstructions







# US Sales and Medical Affairs Executives

Orthocell has appointed two experienced US-based executives, John Walker and Phillip Edmondson, to drive the market launch and sales of Remplir following the expected US FDA market clearance in March / April 2025



**John Walker**

Vice President – Sales

Mr Walker is a highly experienced sales executive, who has successfully led global product launches and sales strategies, most notably helping to lead the growth of nerve repair device sales at Axogen.



**Phillip Edmondson**

Vice President – Medical Affairs

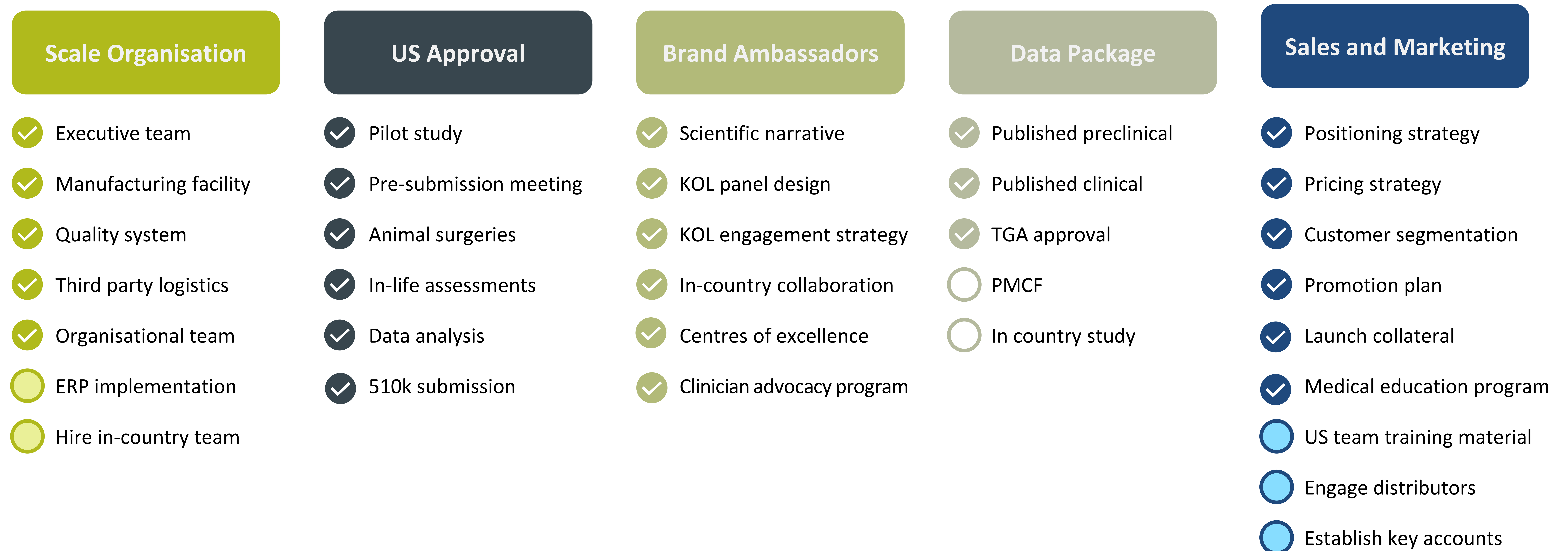
Mr Edmondson is an award-winning medical affairs professional, who excels in creating product awareness, building advocacy and implementing successful medical education programs that contribute to sales growth.





# Remplir™: Path to partnering

Orthocell is underpinned by a proven business model for innovating, developing, launching and successfully partnering medical device products







# Remplir™: Pre-launch completed

**Orthocell successfully completed a pre-launch** program at the 2025 IFSSH and IFSHT Triennial Congress in the US in advance of FDA approval. Attended by leading peripheral nerve surgeons from the US and other countries.

**2025 IFSSH and IFSHT Triennial Congress**  
**WASHINGTON, D.C. USA**



**2025 IFSSH and IFSHT Triennial Congress**

International Federation of Societies for Surgery of the Hand  
International Federation of Societies for Hand Therapy



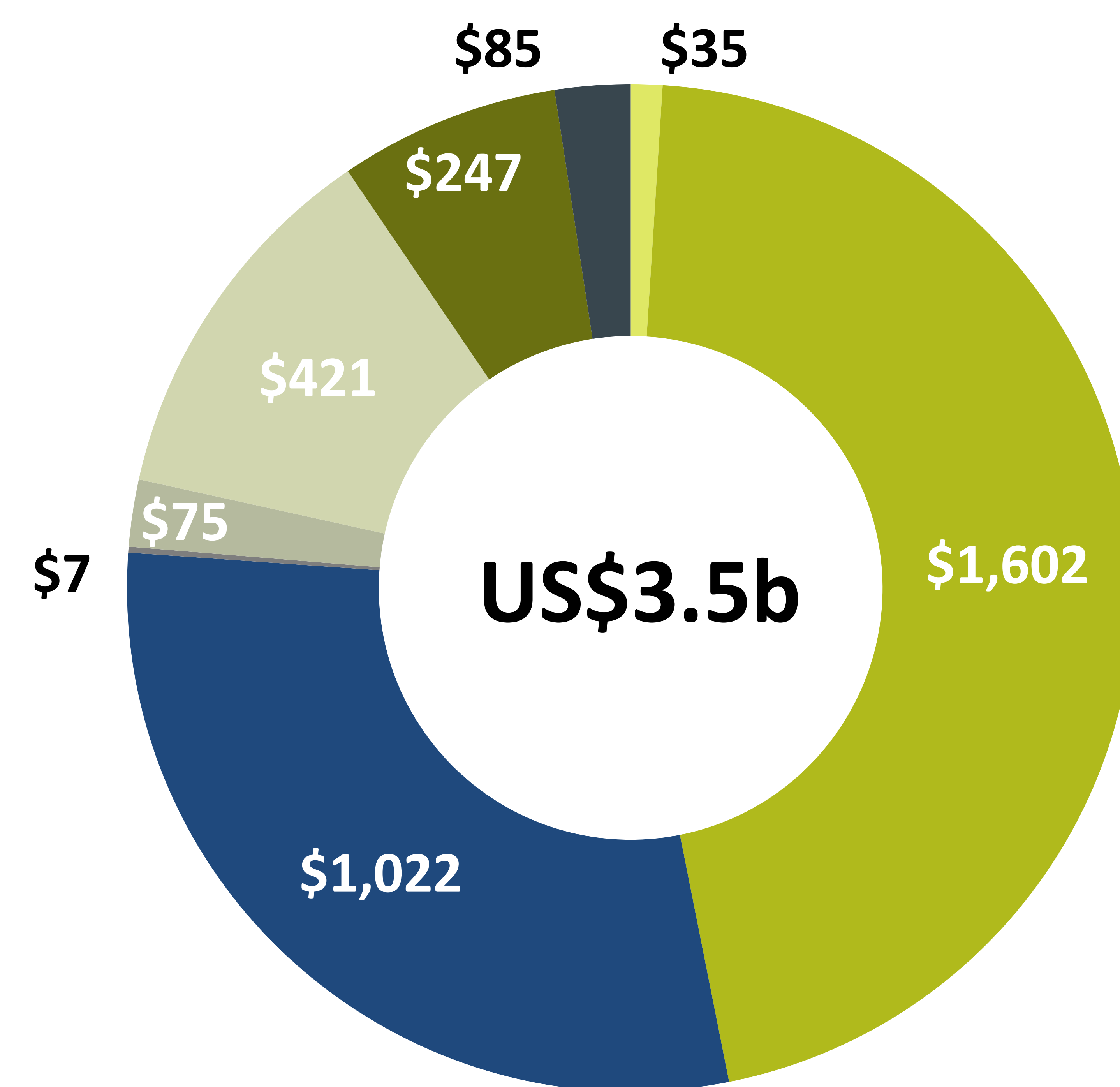




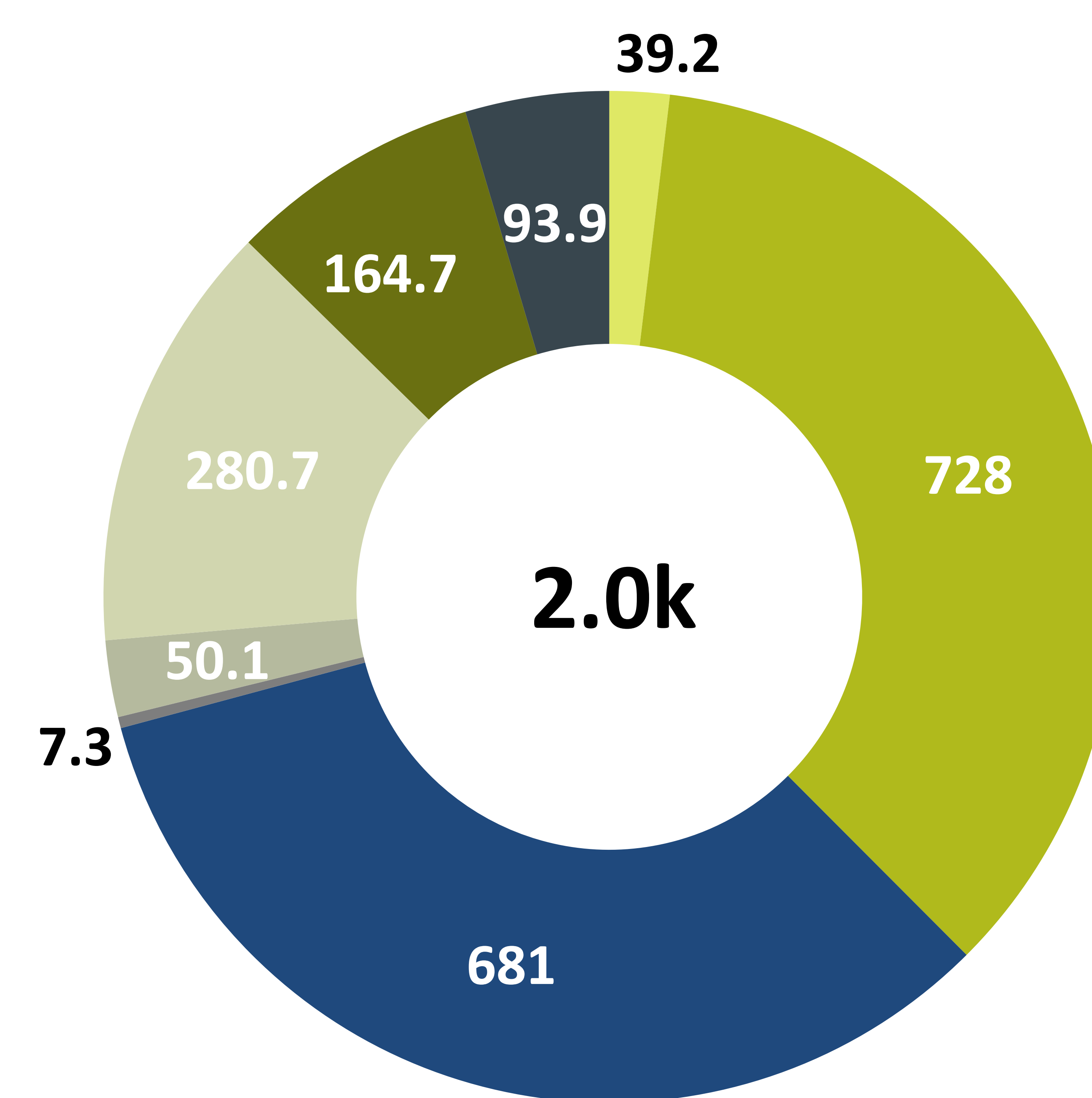
# Remplir™: Large addressable market in nerve reconstruction

Remplir is a breakthrough product on track to be the global market leader in peripheral nerve repair – a retail market estimated to exceed US\$3.5 billion<sup>1</sup> per annum

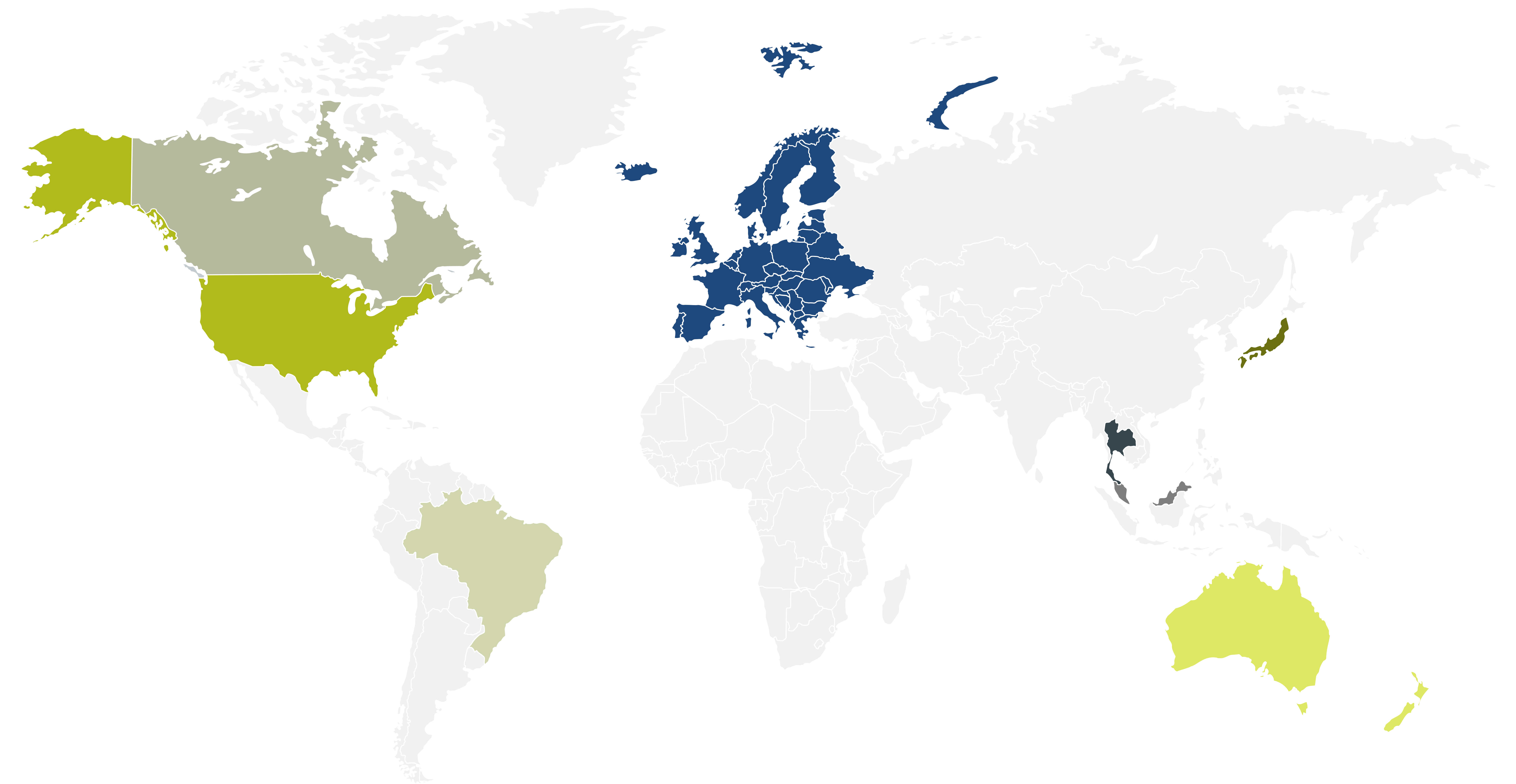
Total Addressable Retail Market (US\$m)



Est. procedures p.a. at peak ('000)



AU/NZ USA EU/UK SGP CAN BRZ JAP THA



Targeting a 20% share of the US\$3.5 billion total addressable retail market

1. Addressable markets include AUS,USA, EU/UK, SGP, CAN, BRZ, JAP, THA. Referenced papers were used to estimate procedures per annum. Papers used included both US and OUS databases and studies





# Remplir™: Market Expansion

Regulatory approval for Remplir in Singapore achieved in 2H CY24 with a further four applications planned in EU, UK & Brazil in the next 6-12 months

APPROVED in Australia, New Zealand and Singapore										
REGULATORY APPLICATIONS	2024	2025				2026				
	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
USA	Submitted	Expected Approval								
Canada		Submitted				Expected Approval				
Thailand		Submitted			Expected Approval					
EU + UK				Planned Submission						Expected Approval
Brazil					Planned Submission					Expected Approval





# Upcoming catalysts<sup>1</sup>

## Remplir – redefining nerve repair

US FDA market clearance

2Q CY25

Appoint US sales team

2Q CY25

Appoint US distributors

2Q CY25

US first sales

2Q CY25

EU+UK & Brazil submissions lodged

3Q / 4Q CY25

## Striate+ – growing better bone

Germany, Austria, Switzerland market launch

Achieved

Singapore product registration

Achieved

Brazil product registration

2Q CY25

Columbia submission lodged

2Q CY25

1. Timelines may be subject to change due to circumstances not under the Company's control





# Key Investment Highlights



**Commercial-stage** medical device company at revenue inflection point



**Best in class** products for Bone, Nerve and Tendon repair



**Strengthened board** with the appointments of highly experienced executives John Van Der Wielen, Professor Fiona Wood and Kim Beazley



**~\$32M cash at bank, strengthened register, no royalty liabilities and funded to US approval** of breakthrough nerve repair device



**Near term value drivers** including Remplir US 510(k) market clearance April CY25





**Authorised for release by:**

**Co-Founder and Managing Director, Paul Anderson**

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E: [paul.anderson@orthocell.com.au](mailto:paul.anderson@orthocell.com.au)

[orthocell.com](http://orthocell.com)







# HealthInvest

April 2025

#HealthInvest



Presenter

**DOUG WARD**  
CEO & MANAGING DIRECTOR



#HealthInvest

HealthInvest April 2025





# Lumos Diagnostics Holdings Limited

## HealthInvest 2025

2 April 2025

*Financial information is shown in USD unless otherwise stated.*

[www.lumosdiagnostics.com](http://www.lumosdiagnostics.com)



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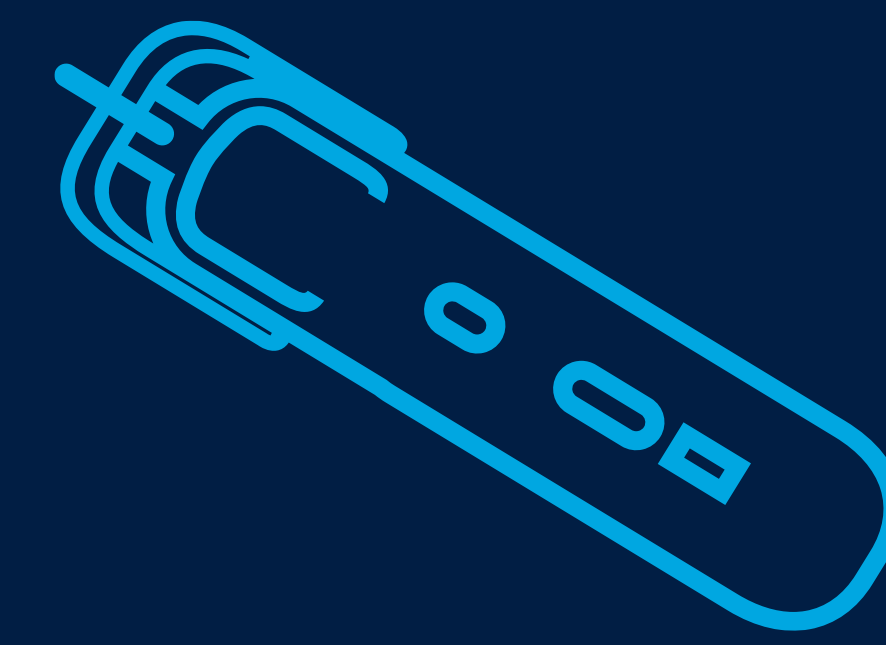
**Who is Lumos  
and why  
do we exist?**

**Lumos develops, manufactures  
and distributes innovative  
diagnostic products**  
– delivering actionable  
information, in real time,  
**at the point-of-care.**

**Improve the practice of medicine**



# Unique Value Creation



Developed and launched one of a kind proprietary point-of-care diagnostic products - FebriDx



Transformational development agreements with world's leading global women's health company – Hologic

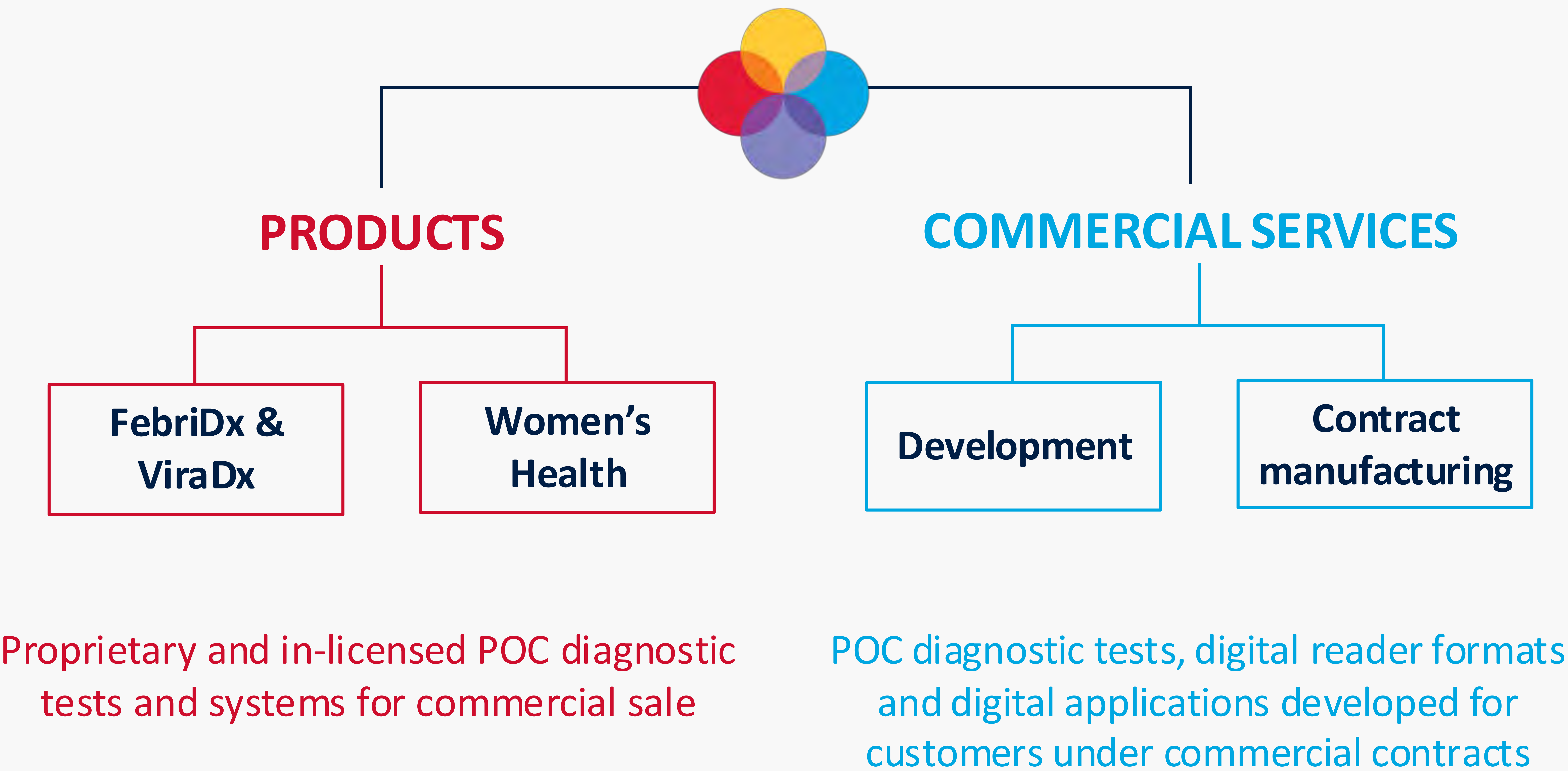


Currently developing women's health and sexual health point-of-care products for point of care



# Lumos Business Overview

Lumos offers end-to-end point of care (POC) diagnostic test development, from initial assay creation to high-volume manufacturing. We develop and sell our own tests and also create tests for customers under commercial contracts.



**Able to leverage R&D, manufacturing scale, and regulatory skillset across Lumos' Products and Commercial Services divisions**



# FebriDx® A Simple And Unique Test For Microbial Infection



FebriDx® can rapidly identify patients who have a microbial infection<sup>1</sup> and, if positive, determine if that infection is caused by a viral or bacterial pathogen after 10 minutes

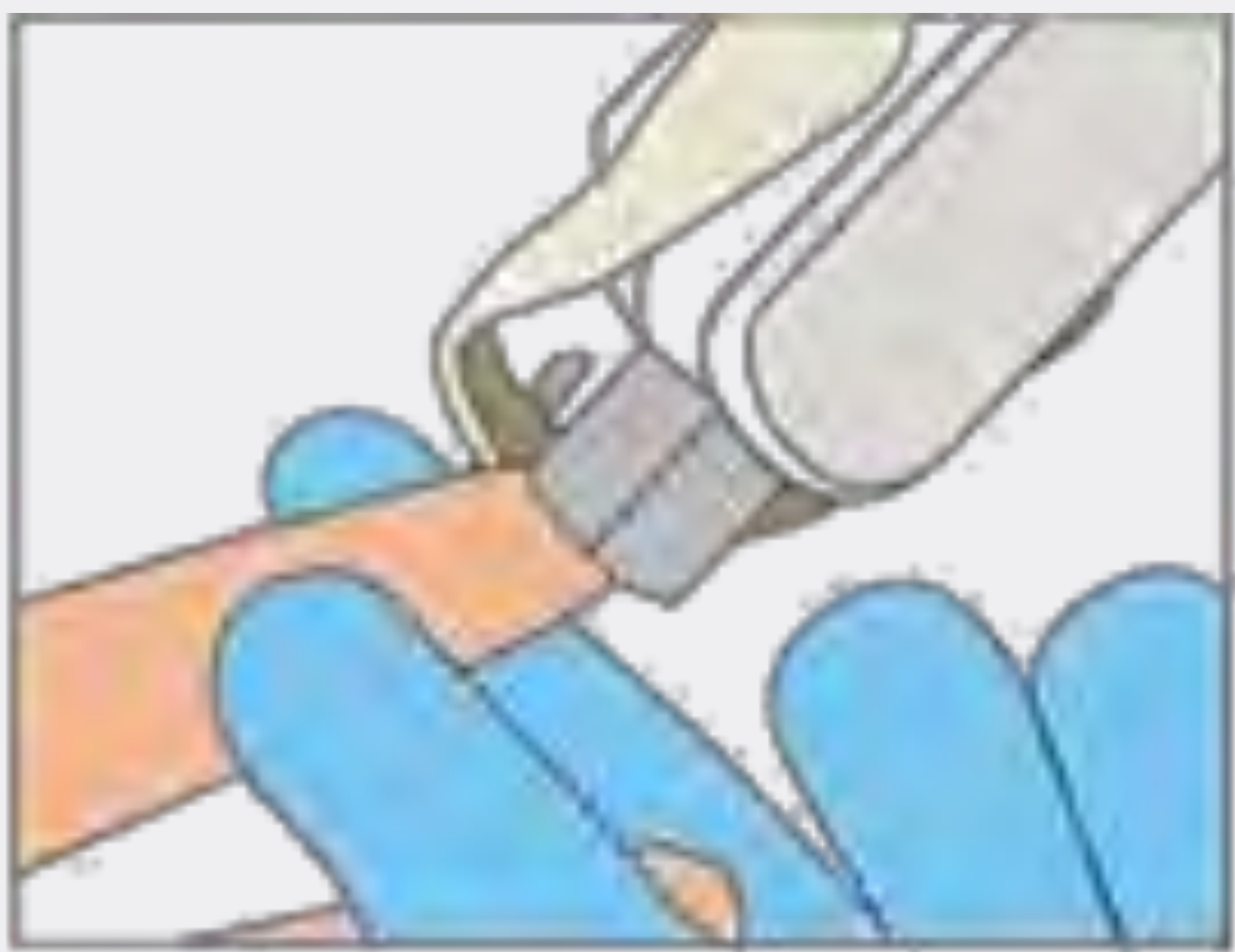


## Key: Markers for infection



CRP Inflammatory marker elevated with any infection  
MxA Specific marker only elevated with viral infection

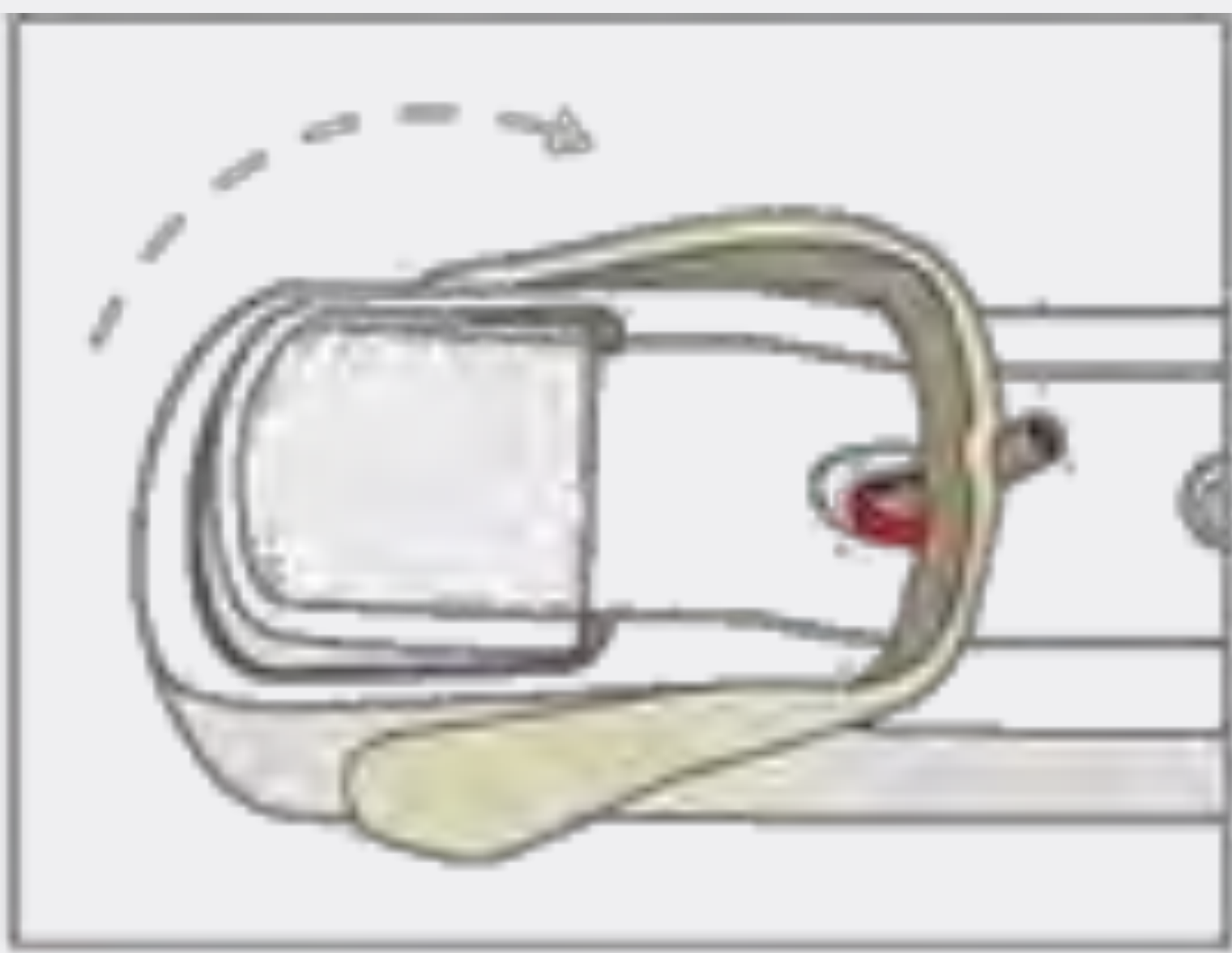
## FebriDx® Test Procedure and Interpretation of Results



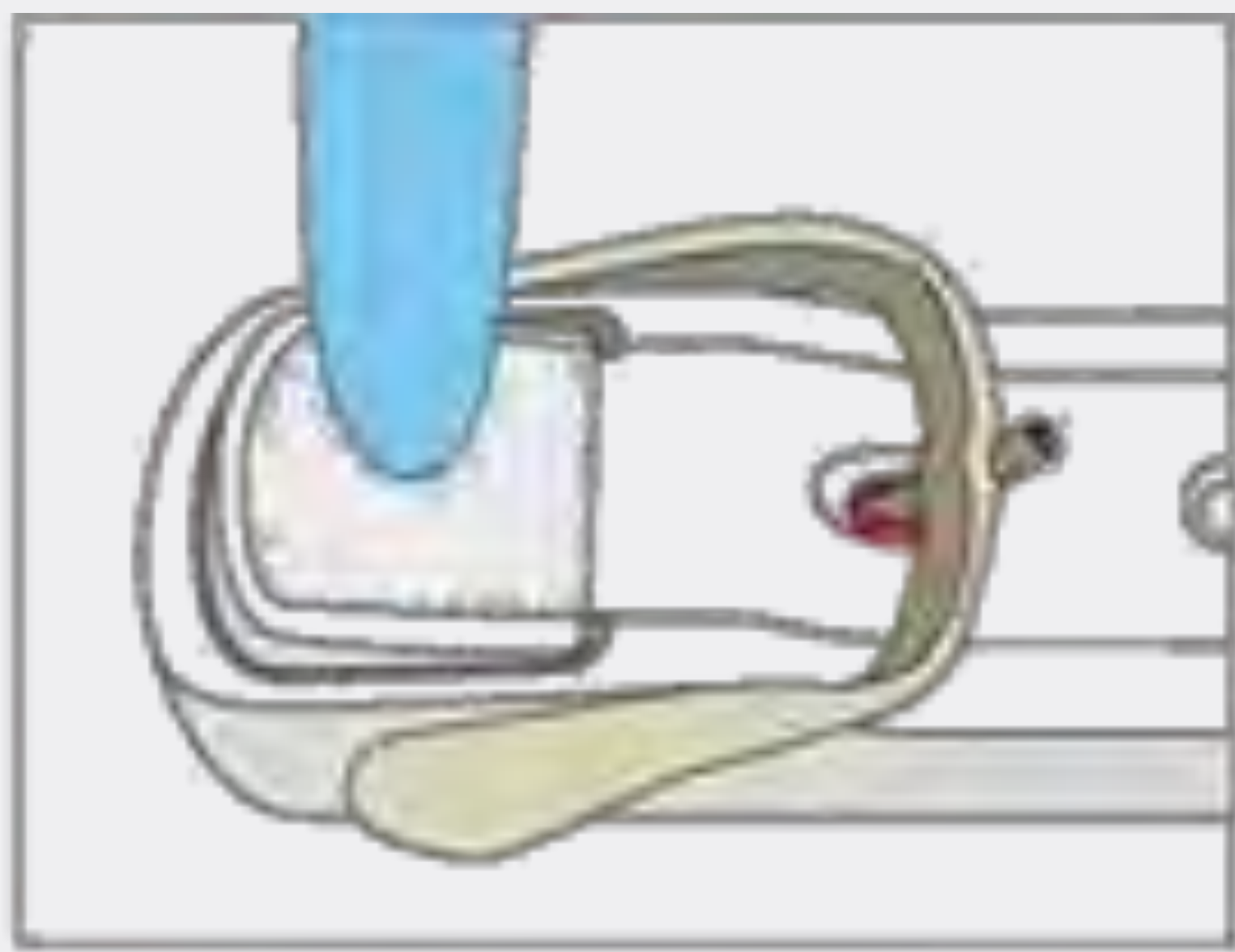
1 Lance finger



2 Collect blood sample



3 Deliver blood sample



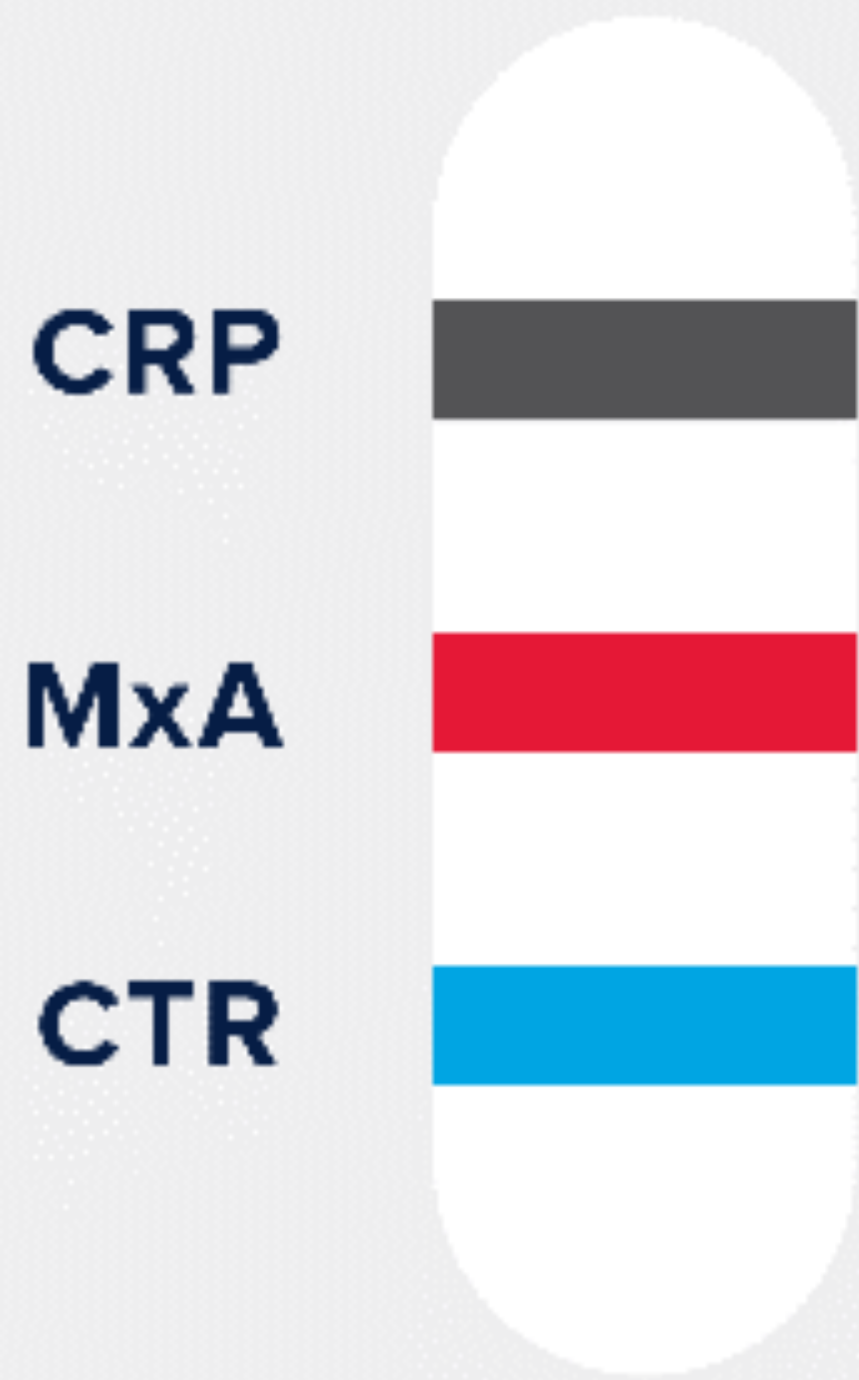
4 Deliver buffer solution

### BACTERIAL INFECTION



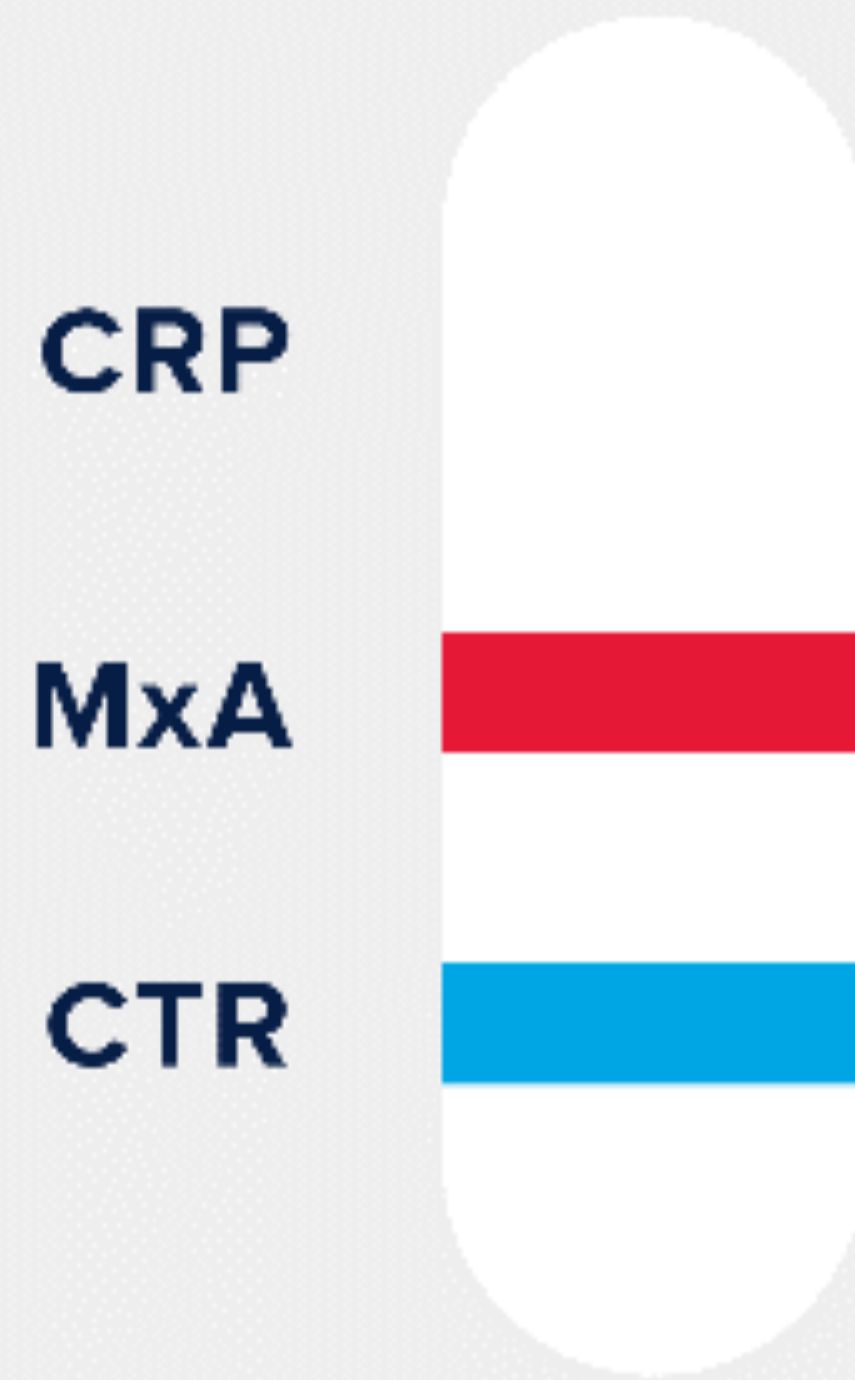
Patient can be treated with antibiotics

### VIRAL INFECTION



Viral Infection - Antibiotics will not work  
Patient needs to be managed differently

### VIRAL INFECTION



1. Microbial infection is the invasion of infectious agents into the organism, their multiplication and the reaction of host tissue against these agents. Infectious agents include bacteria, virus, parasite and fungi.



# FebriDx<sup>®</sup> CLIA Waiver Update

## **BARDA partnership agreement | October 2024**

To support CLIA waiver and pediatric studies:  
non-dilutive funding up to US\$8.3m

- US\$3.0m to support CLIA waiver study
- US\$5.3m to support pediatric study (children under 12yrs old)
- Payments based on achieving certain milestones

## **CLIA waiver clinical study commenced | December 2024**

- Trial commenced on 19 December 2024 - first patient tested
- Around 350 patients tested to-date
- Bacterial prevalence lower than expected
- Implementing patient enrollment “enrichment” plan
- Anticipate completion in 2H CY2025

## **Access to \$1Billion market opportunity**

- Expands the TAM from 18k to around 270k clinical sites
- 15x increase to over \$1Billion





# Lumos Future Products

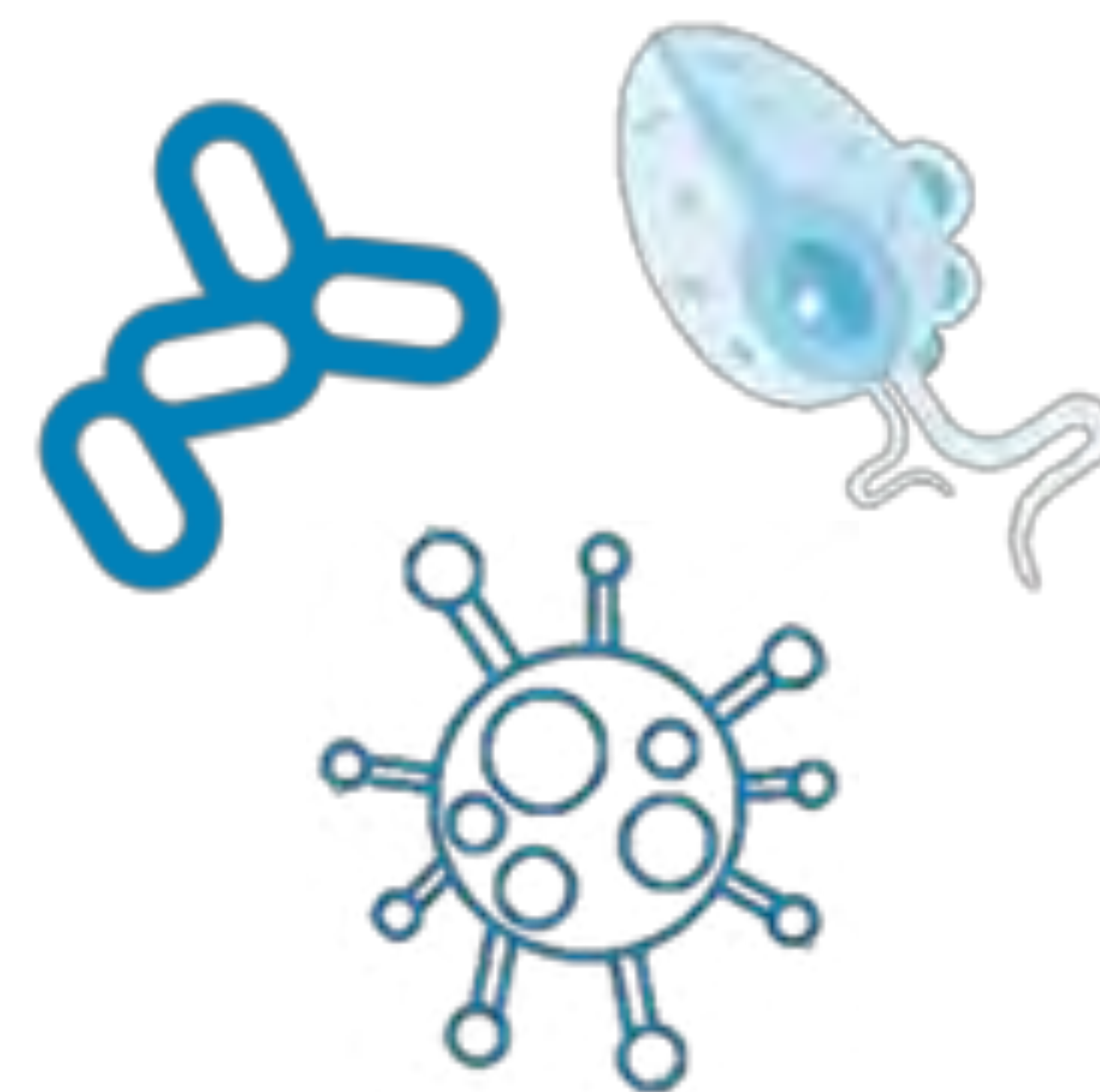


Women's Sexual Health - \$10B



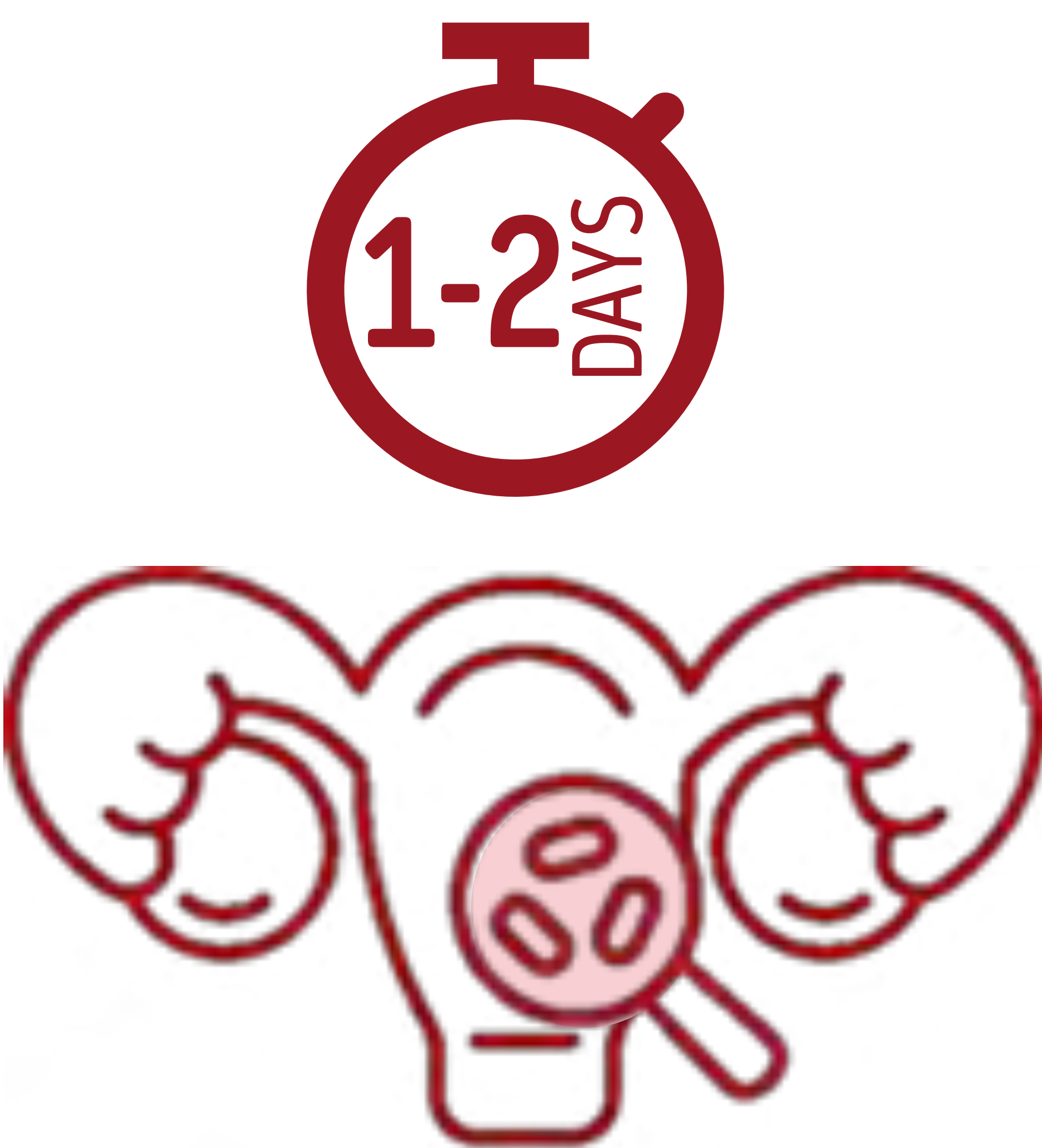
## Prevalence

30-40% of women  
>10M health care visits annually



## Clinical Need

Multiple infectious organisms  
Similar symptoms  
Different treatments



## POC Diagnostic Need

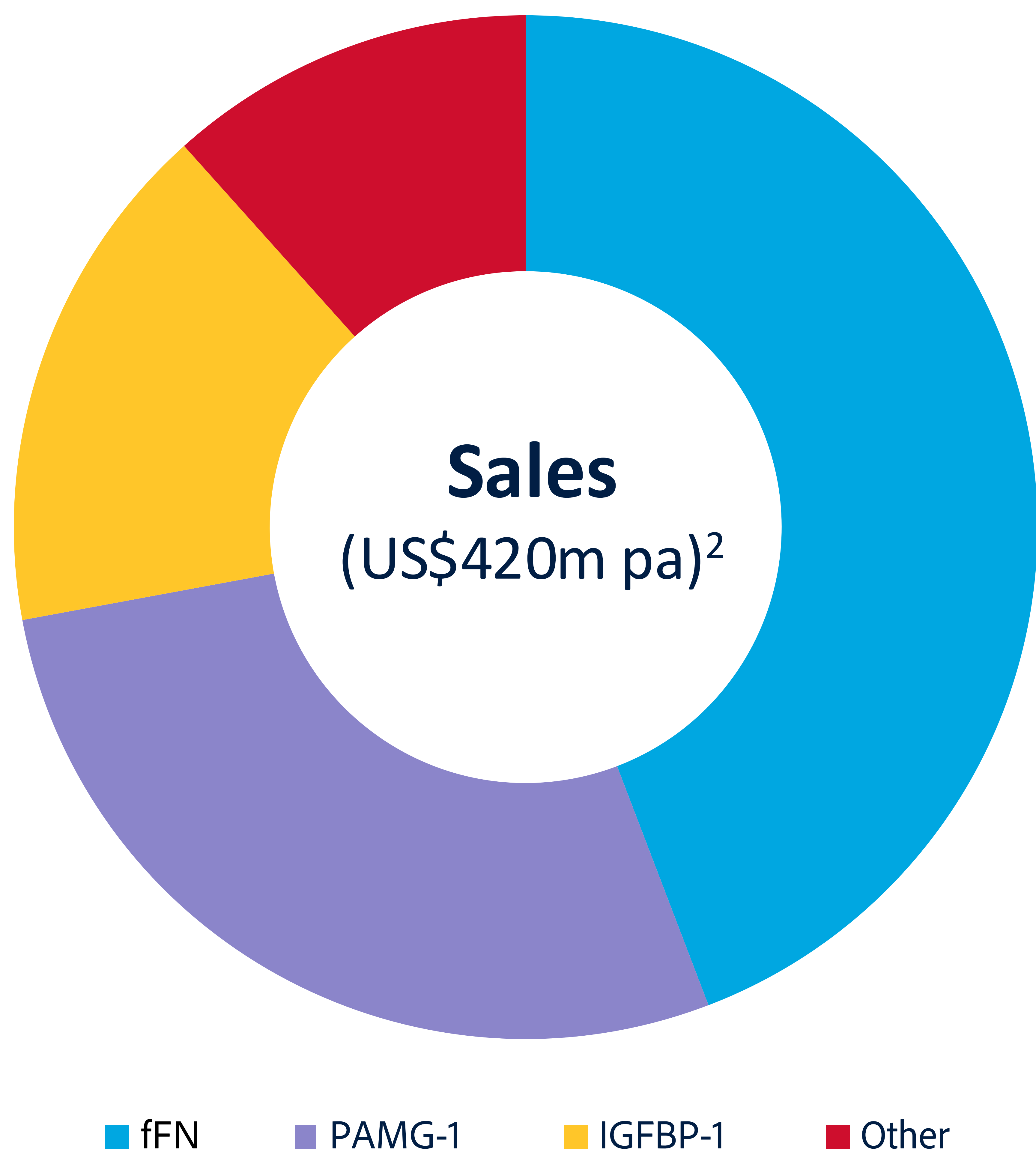
Rapid testing on site  
Identify & treat at patient visit  
Easy to use by clinic staff



# Hologic - Strategic Partnership

Fetal Fibronectin (fFN)<sup>1</sup>

fFN is a biomarker indicating a heightened risk of pre-term delivery and is the largest segment of the pre-term birth diagnostic kit market



2. Global Market Insights, [www.gminsights.com](http://www.gminsights.com)



Current test:  
Rapid fFN TLiQ



Next generation test  
concept (mock-up)





# Key Priorities

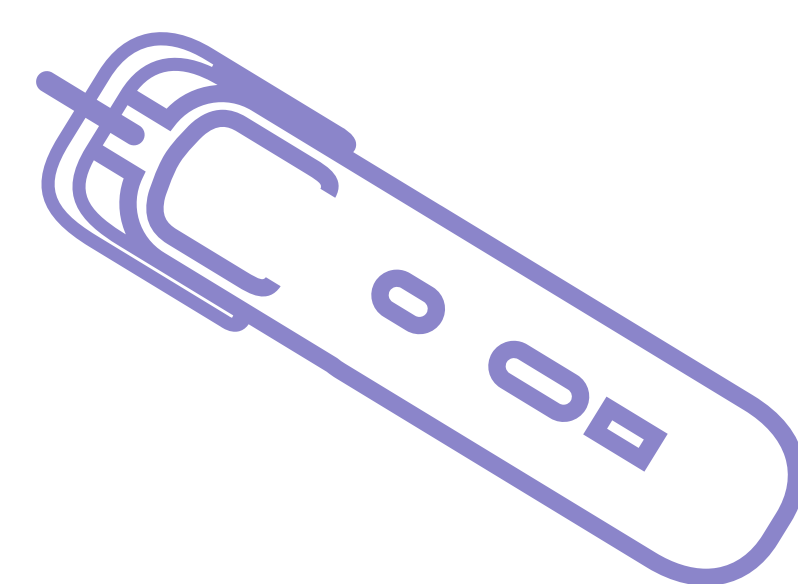
A horizontal bar composed of several small, colored rectangular segments in yellow, red, blue, purple, and orange.



# Key Priorities



Implement bacterial positive enrichment strategy for FebriDx CLIA waiver trial to speed up the study



FDA pre-submission for FebriDx pediatric study in April 2025



Continue to drive FebriDx product awareness and sales into US urgent care centers



Deliver on Hologic fFN development milestones - milestone 2 from Phase 2 & Phase 3 milestones



Progress to formal product development on the first Lumos branded women's health diagnostics test





[www.lumosdiagnostics.com](http://www.lumosdiagnostics.com)





# HealthInvest

April 2025

#HealthInvest



Presenter

**NINA WEBSTER**

CEO AND MANAGING DIRECTOR



#HealthInvest

HealthInvest April 2025





# Dimerix

(ASX:DXB)

## HealthInvest Summit

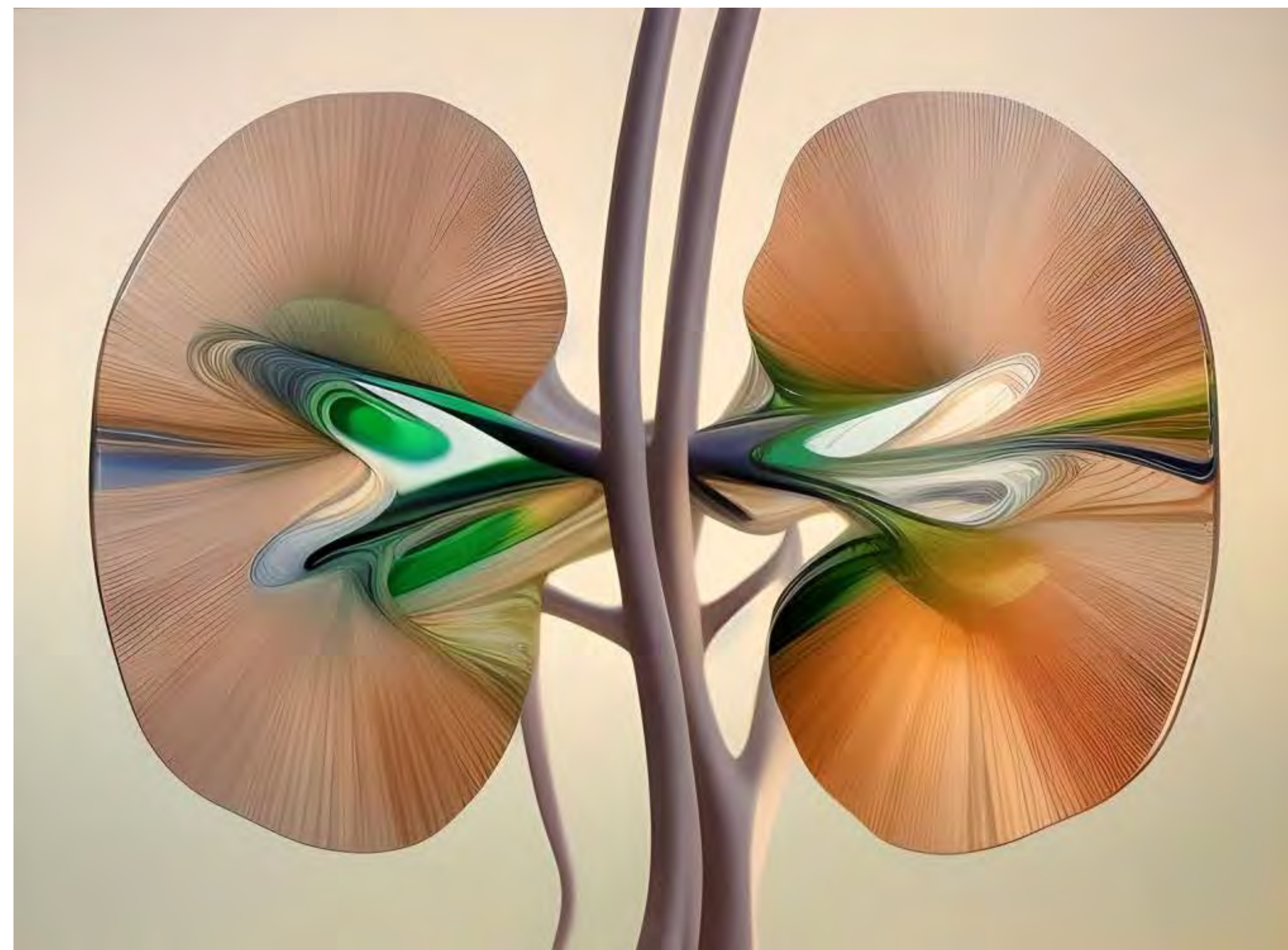
*Sydney – 2 April 2025*

*Authorised for lodgement by the Board of the Company*

PRESENTED BY: *ir department...*

**STOCKHEAD**

 **morgans**



*Developing new therapies to treat inflammatory causes of kidney disease with unmet clinical needs*



# Forward looking statements

*This presentation includes forward-looking statements that are subject to risks and uncertainties.*

*Although we believe that the expectations reflected in the forward looking statements are reasonable at this time, Dimerix can give no assurance that these expectations will prove to be correct.*

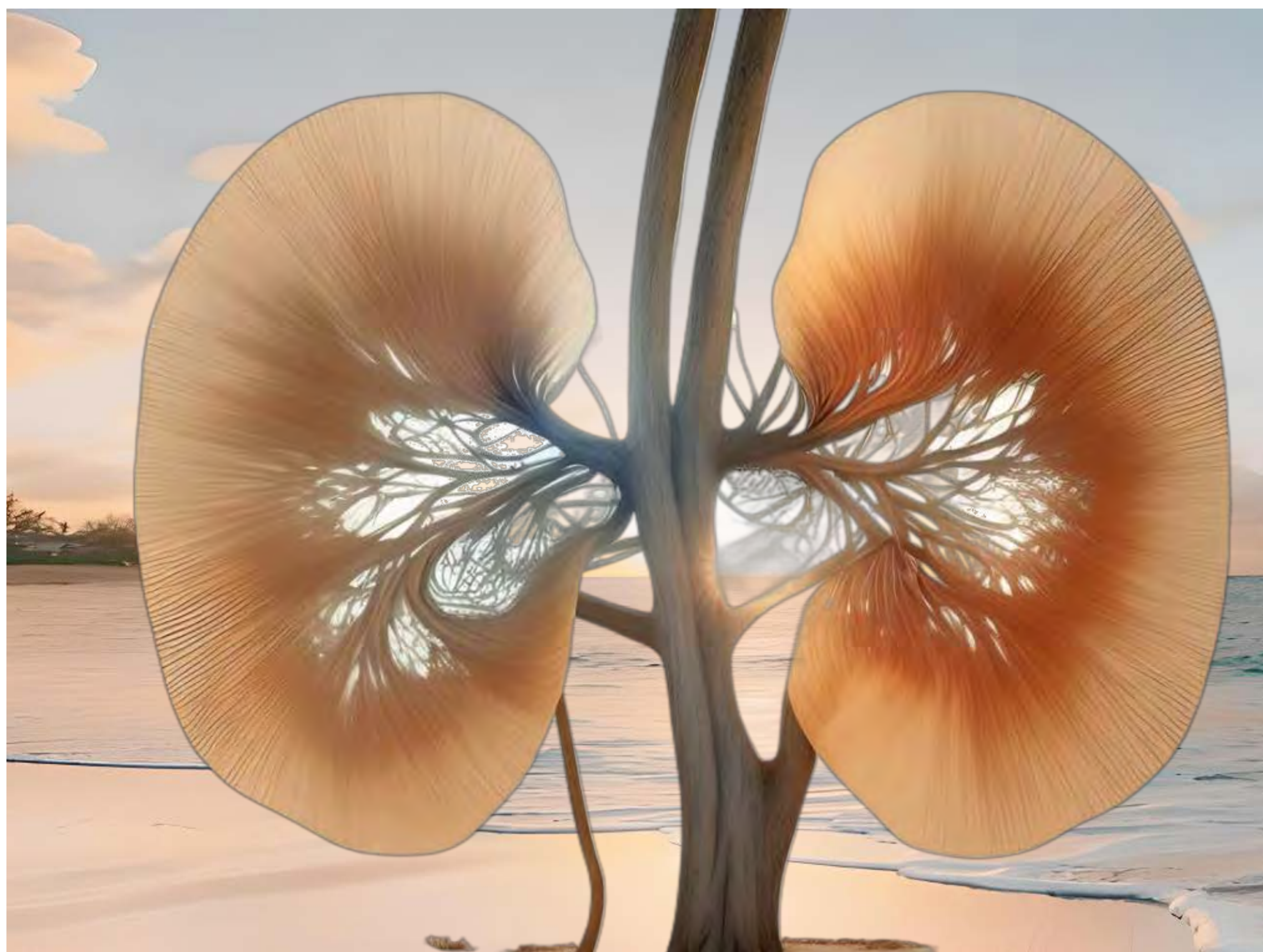
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*Actual results could differ materially from those anticipated. Reasons may include risks associated with drug development and manufacture, risks inherent in the regulatory processes, delays in clinical trials, results of clinical trials, risks associated with patent protection, future capital needs or other general risks or factors, along with those factors outlined in the most recent Dimerix Limited Annual Report.*



# Overview | Phase 3

# Global Opportunity



## Lead Drug Candidate

- DMX-200 is currently in a **Phase 3 clinical trial** for focal segmental glomerulosclerosis (FSGS)
- DMX-200 has **orphan drug designation** in key territories



## FSGS Indication

- FSGS is a **rare disease** that causes scar tissue of kidneys, which leads to irreversible kidney damage<sup>1</sup>
- FSGS kidney damage can lead to dialysis, kidney transplants or death<sup>1</sup>
- There are currently **no approved treatments** available to treat FSGS



## Commercial and Technical Validation

- **Three commercial licensing deals** achieved:
  - ~\$458m in total upfront & potential milestone payments + royalties<sup>2</sup>
- **Successful Phase 3 interim analysis**: Analysis showed DMX-200 had performed better than placebo in reducing proteinuria<sup>3</sup>





# Focal Segmental Glomerulosclerosis (FSGS)

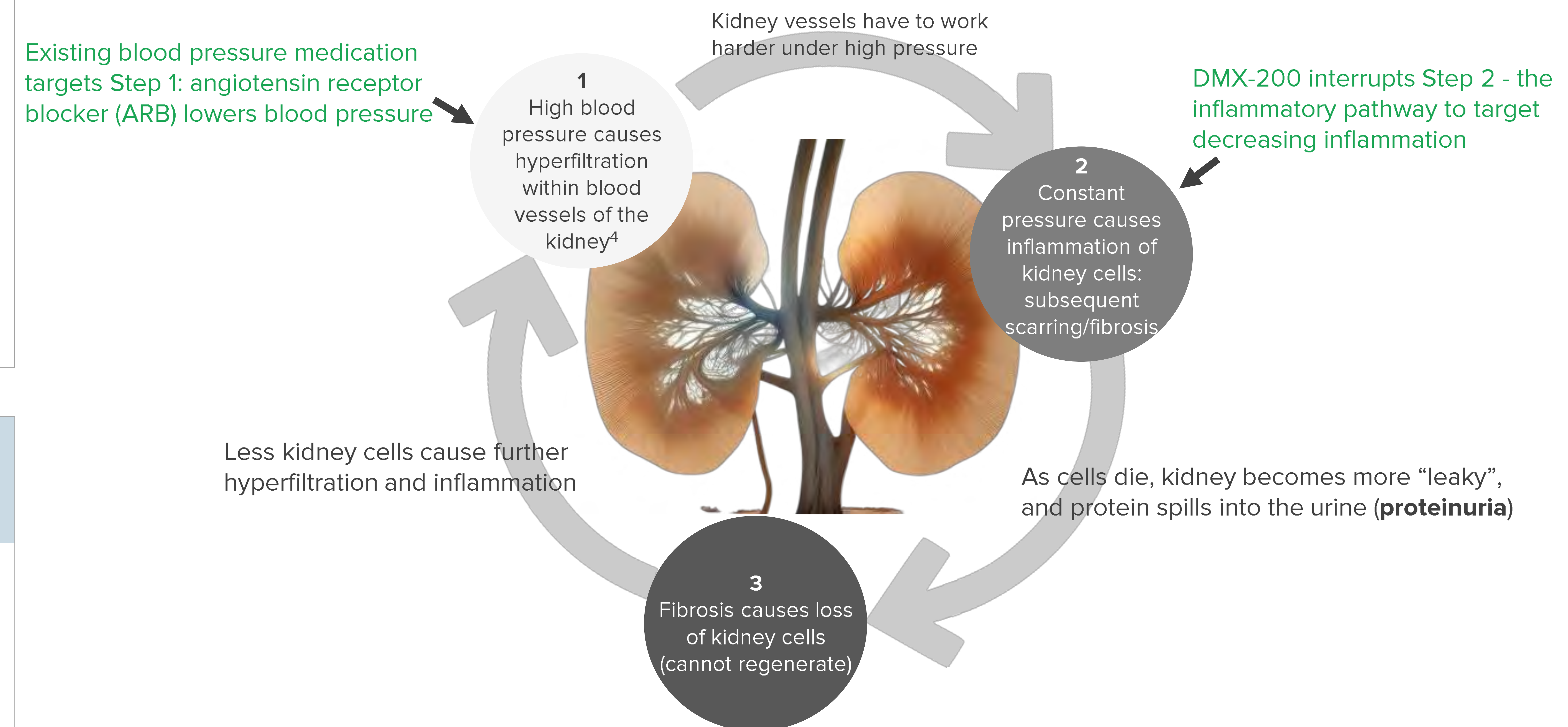
## What is FSGS?

**Focal** = some  
**Segmental** = sections  
**Glomerulo** = of the kidney filtering units  
**Sclerosis** = are scarred

## How do you measure kidney function?

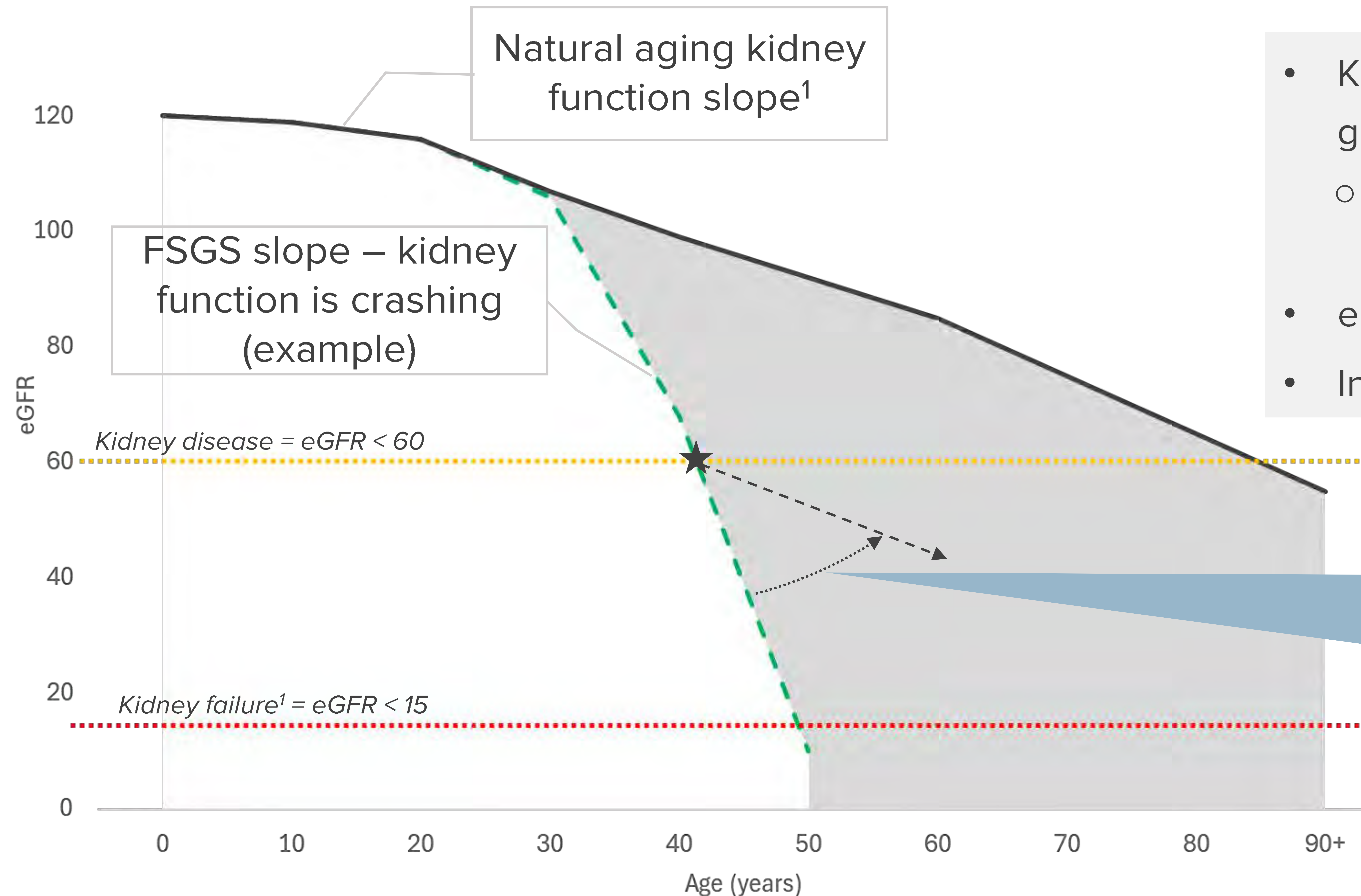
- Historically, measured using “hard” endpoints for kidney disease (kidney failure) -which may not be reached for decades<sup>1</sup>
- Regulatory agencies and national bodies now consider estimated glomerular filtration rate (eGFR) and proteinuria decline as surrogate end points for kidney failure in certain conditions<sup>2</sup>

## FSGS Kidney Damage<sup>3</sup>





# Significance of stabilising eGFR curve: primary endpoint



- Kidney function can be measured using estimated glomerular filtration rate (eGFR):
  - how many millilitres of blood is filtered by the kidney per minute
- eGFR slope naturally declines as we age<sup>1</sup>
- In FSGS patients, it is crashing

Treatments, such as DMX-200, aim to bring the FSGS slope back up towards that which occurs with natural aging:

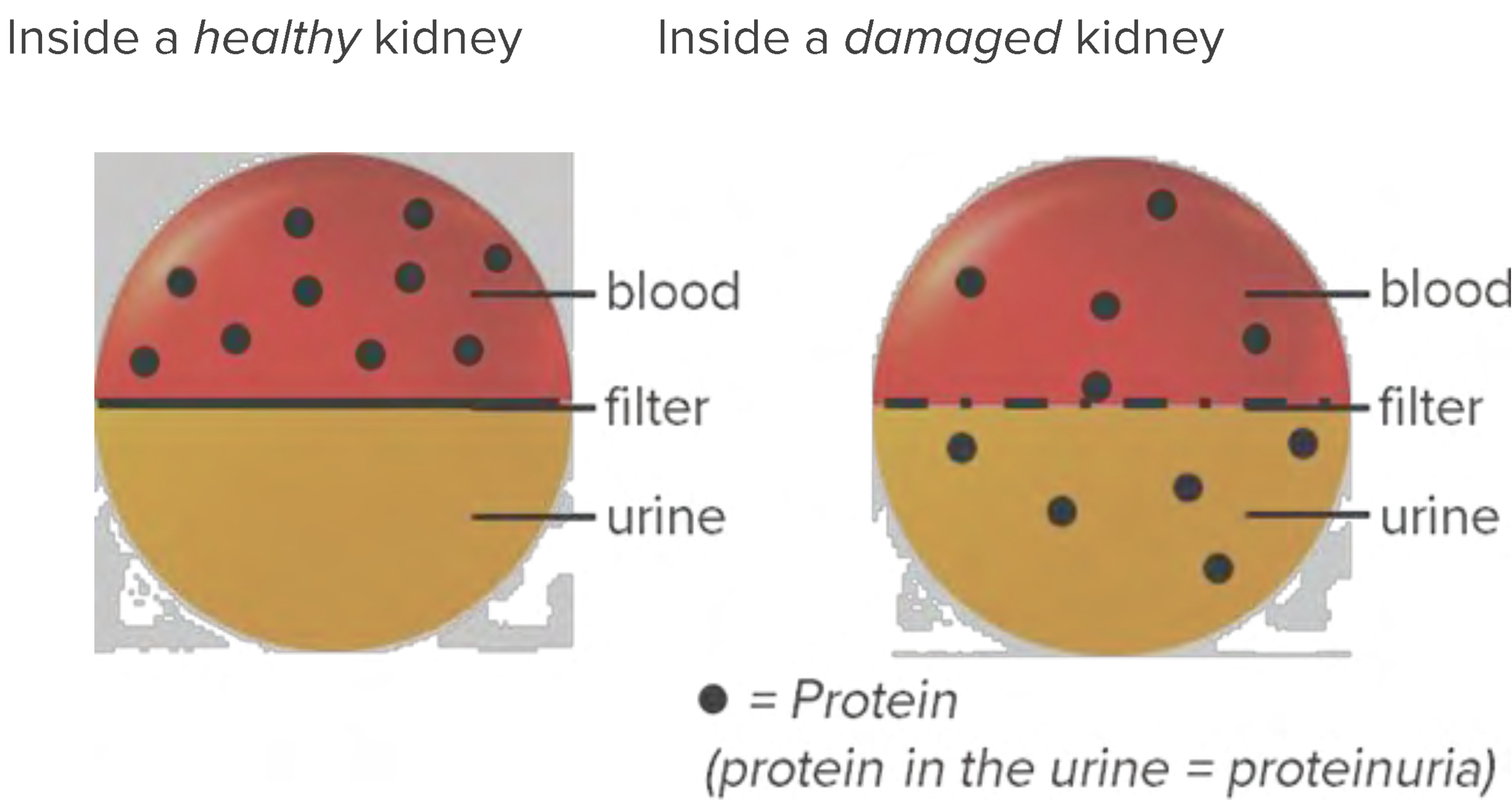
- This can add years to the life of the kidney
- Potential to delay dialysis and/or kidney transplant



# Significance of decreasing proteinuria: primary endpoint





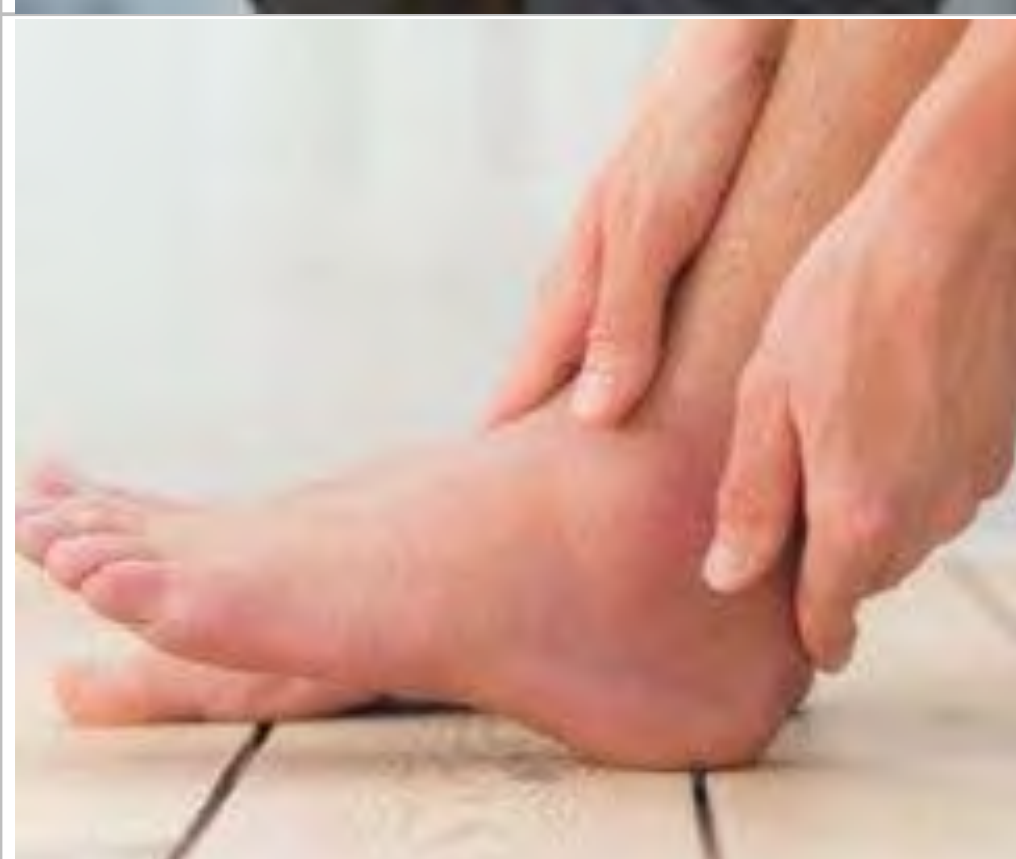




## Why are kidneys important?

- A healthy kidney is a good filter and allows little to no protein in the urine<sup>1</sup>



- When kidneys are damaged, protein can leak into the urine causing proteinuria
- Proteinuria represents an important early marker of kidney function<sup>2</sup>

## Symptoms of proteinuria

	More frequent urination		Shortness of breath
	Nausea and vomiting		Tiredness
	Swelling in the face, stomach, feet and/or ankles		Lack of appetite
	Muscle cramping at night		Foamy or bubbly urine
	Puffiness around the eyes, especially in the morning		

DMX-200 aims to reduce the inflammation of the kidneys:

- if DMX-200 reduces inflammation, the amount of proteinuria should decrease





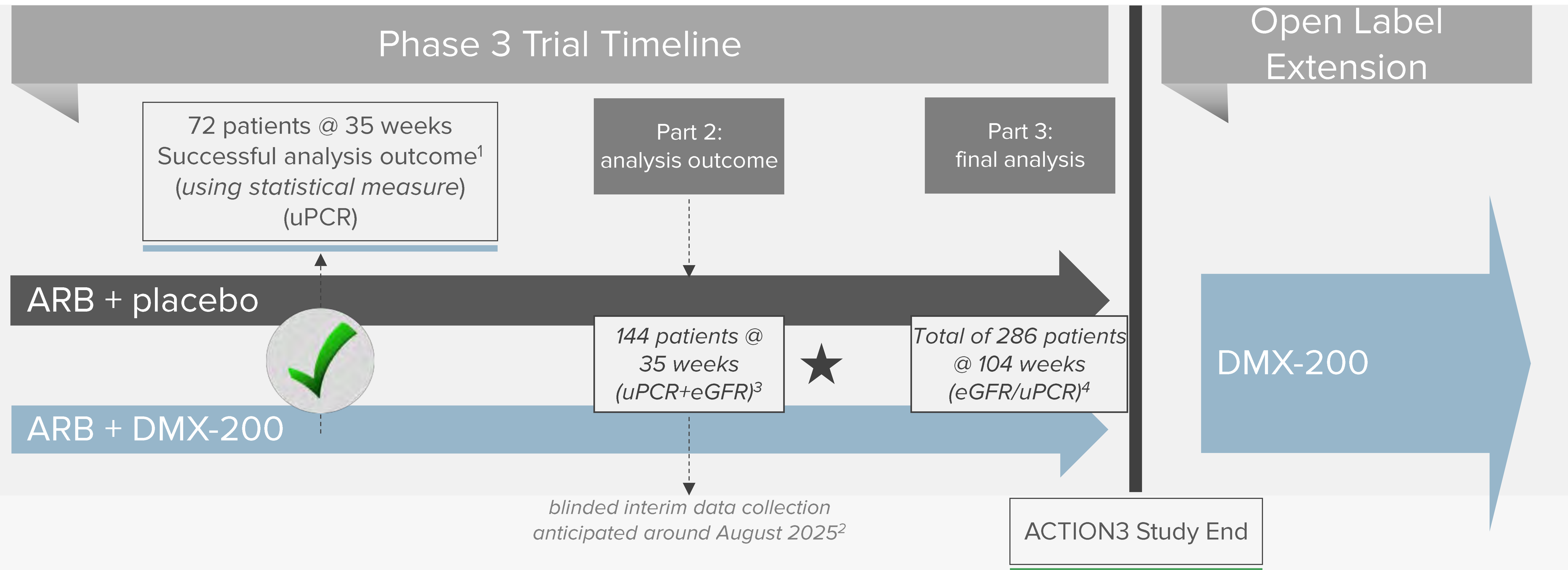
# phase 3 clinical trial – next steps

A randomised, double-blind, multi-centre, placebo-controlled study of renal outcomes of DMX-200 in patients with FSGS receiving an ARB

## Background

- Patients recruited, then screened and stabilised on background medications
- Patients randomised to receive drug or placebo
- DXB remains blinded at all times during study

## Phase 3 Trial Timeline

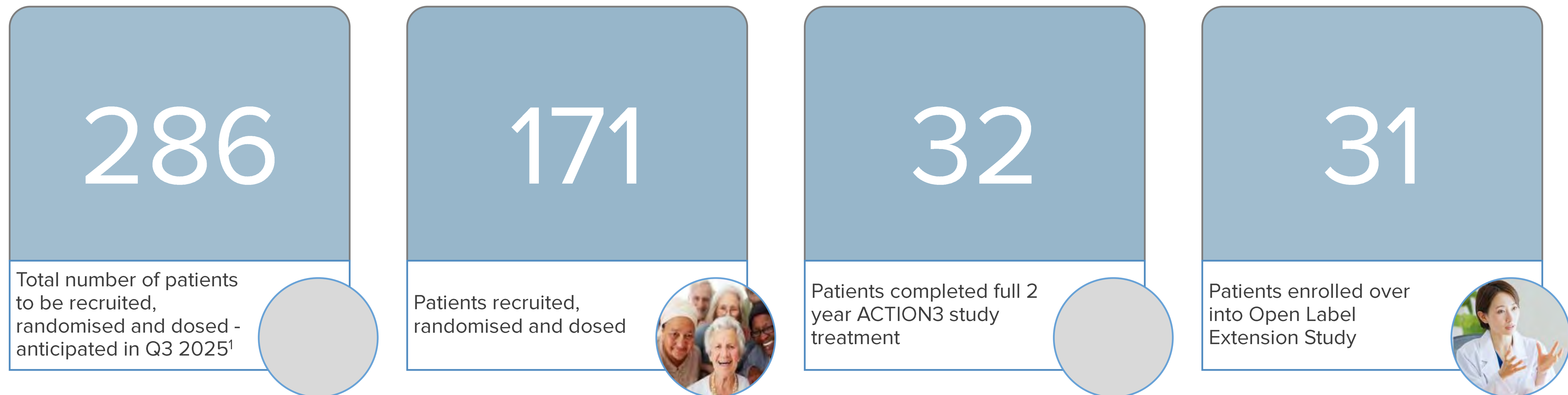


★ Potential to submit for conditional marketing approval <sup>3</sup>



# ACTION3 current status

FSGS CLINICAL STUDY



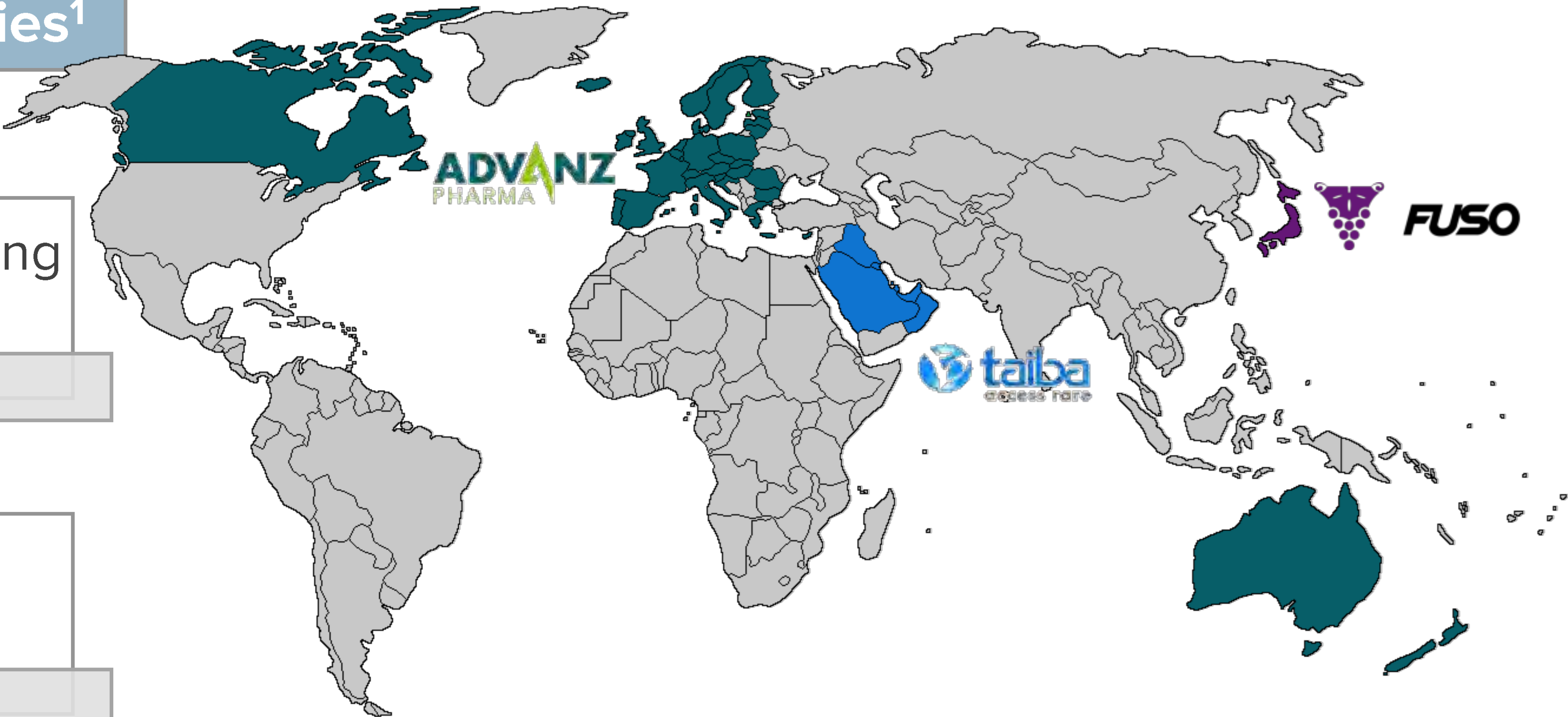
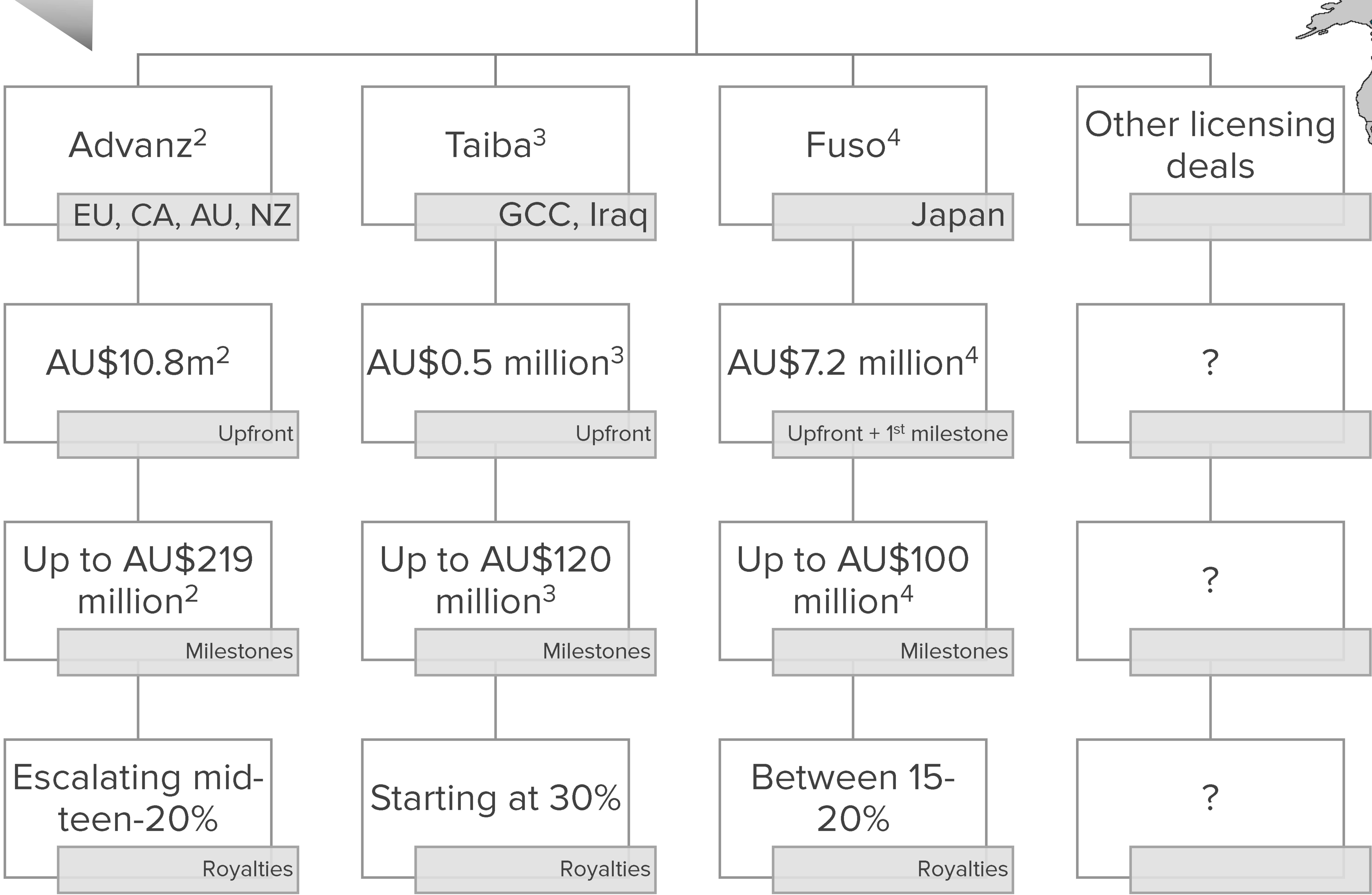
## Confirmed:

- Positive Type C meeting held in March 2025 with US Food & Drug Administration (FDA) on proteinuria trial endpoints, and potential for accelerated approval for DMX-200
- Dimerix intends to update the market on meeting outcomes upon the receipt of the formal FDA meeting minutes - anticipated within 30 days of the meeting (i.e. April 2025)



# Summary of licensing deals

Licensing deals collectively valued up to **AU\$458 million in total upfront and potential milestone fees + royalties<sup>1</sup>**



Significant potential additional global value remains, as Dimerix pursues and progresses licensing opportunities with potential partners outside the licensed territories, including in US and Mainland China

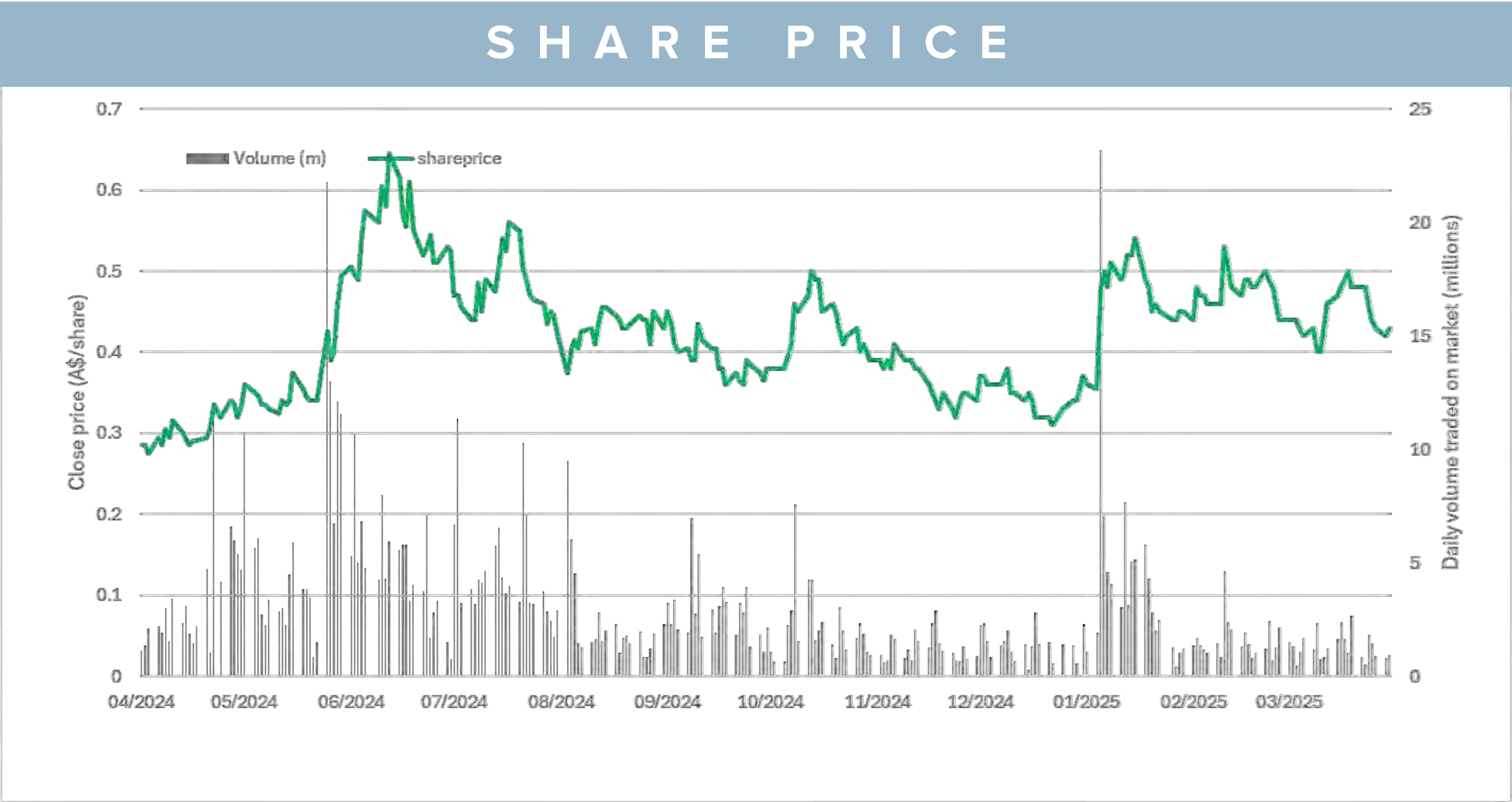


# Corporate overview

Ticker Symbol	ASX: DXB
Cash Balance (Dec24)*	\$21.11 million
Market Capitalisation <sup>1</sup>	~A\$240 million
Share price <sup>1</sup>	~A\$0.425
Total ordinary shares on issue <sup>1</sup>	559,251,910
Average Daily Liquidity by value for past 30 trading days <sup>2</sup>	~A\$0.87 million

\*Cash balance does not include:

- ~\$3.1 million - upfront fee received from Fuso development & licensing agreement (ASX release 4 March 2025)
- ~\$4.1 million - payment anticipated on 1st clinical site opening in Japan from Fuso licensing agreement Q2 2025
- Up to \$6.5 million - potential conversion of 41,920,587 DXB options (as at 31 December 2024) exercisable at 15.4c per share (expire 30June2025)

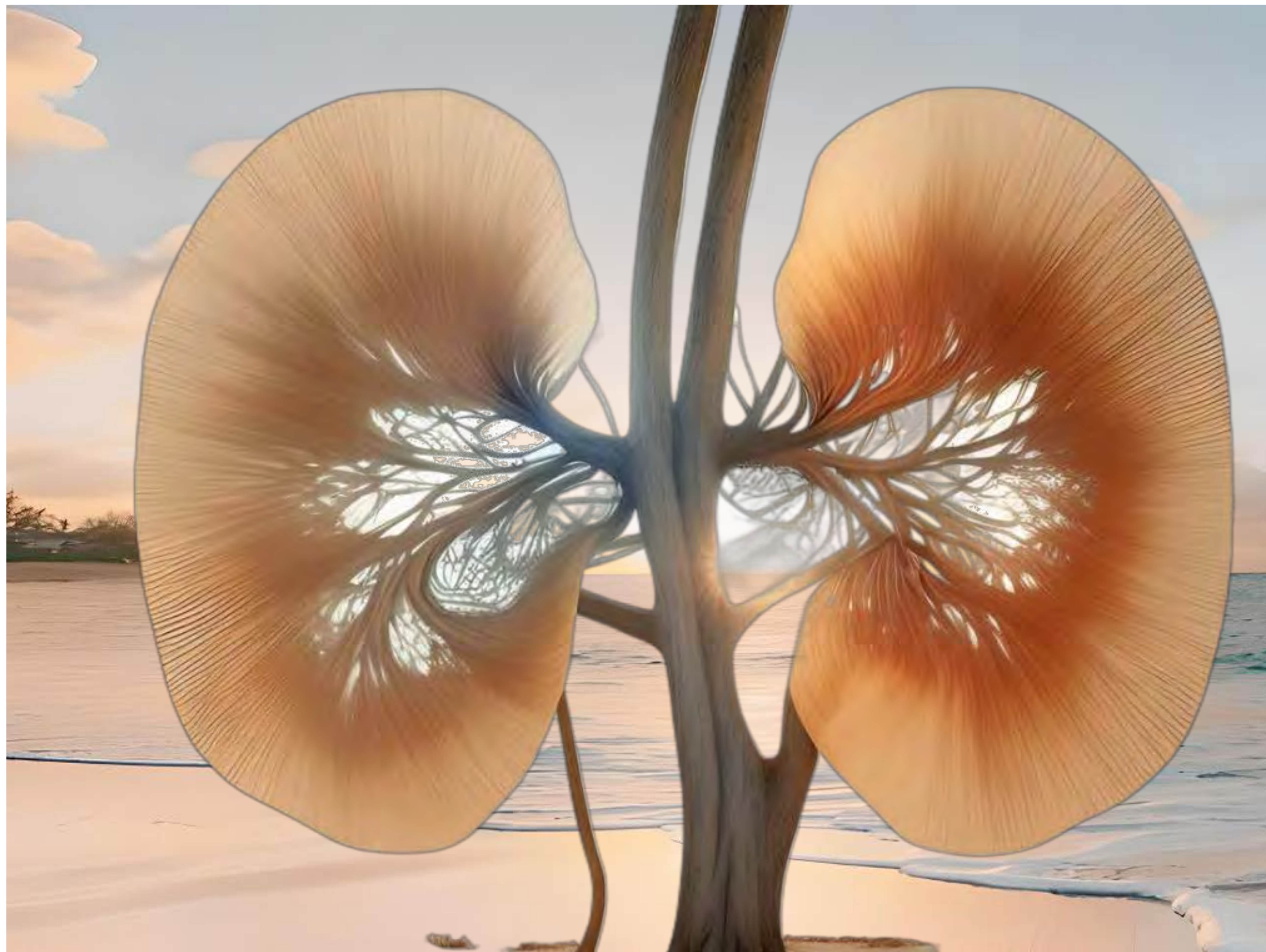


SUBSTANTIAL SHAREHOLDERS <sup>3</sup>			
Position	Holder Name	Holding	% IC
1	Mr P Meurs	75,679,506	13.5%
TOTAL (TOP 5) Shareholders		130,906,002	23.4%

1. As at 1 April 2025; 2. Past 30 trading days liquidity as at 1 April 2025; 3. Shareholder register as at 1 April 2025



# Potential catalysts



## 2025

### Q1/Q2 2025

- **Complete: FDA meeting** held – formal minutes anticipated April 2025<sup>1</sup>
- ~AU\$4.1 million<sup>2</sup> **development milestone** anticipated from FUSO<sup>1</sup>

### Q3/Q4 2025

- Planned blinded **interim data collection** anticipated in August 2025, subject to FDA feedback<sup>3</sup>
- Potential for **accelerated (or conditional) approval** submission, subject to FDA feedback<sup>1,3</sup>
- **Full study recruitment** of 286 adult patients anticipated in CYQ3 2025<sup>3</sup>

### Potential upside – at any time

- Additional **licensing partners** for DMX-200: Dimerix continues to pursue potential licensing opportunities in un-licensed territories, including US & China



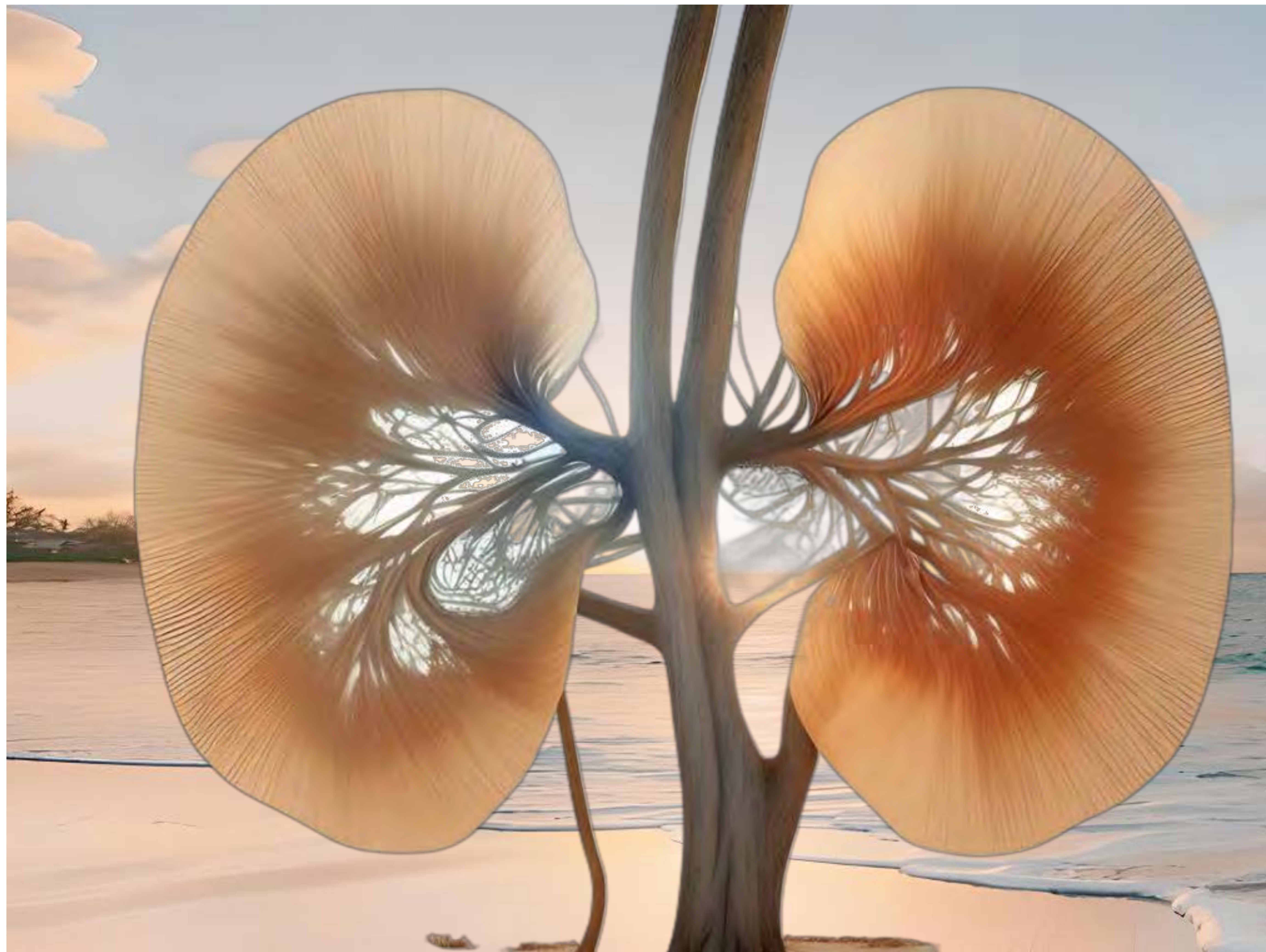


# Dimerix

(ASX:DXB)



## WELL POSITIONED TO DELIVER AGAINST STRATEGIC PLAN



A biopharmaceutical company developing innovative new therapies in areas with unmet medical needs, with a core focus on inflammatory disease treatments such as kidney and respiratory diseases.

### **ESG Statement**

*Dimerix is committed to integrating Environmental, Social and Governance (ESG) considerations across the development cycle of its programs, processes and decision making. The Dimerix commitment to improve its ESG performance demonstrate a strong, well-informed management attitude and a values led culture that is both alert and responsive to the challenges and opportunities of doing business responsibly and sustainably.*

### **Dimerix HQ**

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Victoria, Australia  
T. 1300 813 321  
E. [investor@dimerix.com](mailto:investor@dimerix.com)



The background of the slide features a complex molecular structure composed of interconnected hexagons and lines, rendered in various shades of blue. The structure is more prominent in the top-left and bottom-right corners, while the center is dominated by the text.

# HealthInvest

April 2025

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# Q & A

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THANK YOU FOR JOINING

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April 2025



**EM** VISION

**MiCROBA**™

ortho·cell

 **LUMOS**  
DIAGNOSTICS

 **Dimerix**

PRESENTED BY:  ir department...  **morgans**

MEDIA PARTNER: **STOCKHEAD**