

LSI Alumni Innovator Spotlight: Heart Biotech's Francis White



Francis White (Source: LSI Europe '25)

Backed by 30 years of research and a world-first Nature publication, Heart Biotech is transforming the future of heart valve replacement with a regenerative scaffold that grows a living valve inside the body.

Under the leadership of CEO **Francis White**, **Heart Biotech** is developing the *Yacoub Heart Valve*, a groundbreaking solution designed to eliminate the compromises of today's standard of care. Rather than implanting a mechanical or animal-derived valve, the company's platform uses a resorbable scaffold that prompts the patient's body to regenerate fully functional, native cardiac tissue *in situ*.

Decades in the Making

Heart Biotech was founded in 2014 to translate decades of research led by legendary cardiothoracic surgeon, Prof. Sir **Magdi Yacoub**, into clinical reality.

Yacoub, who established the **Magdi Yacoub Institute at Harefield Heart Science Centre**, spent over 30 years exploring how to use tissue engineering to regrow living structures inside the human body.

"Sir Magdi had been working in science as well as surgery, which is quite rare for a surgeon, and he spent 30 years trying to crack the code," said White. "The goal has always been to regrow living tissue inside a patient, rather than implanting metal or plastic that's permanent and carries long-term risks and compromises."

White joined the company in 2024, bringing decades of medtech leadership to a field he describes as transformative. "Most medical devices are

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compromises; they alleviate symptoms but don't restore what's lost," he said. "This is fundamentally different. This is real repair."

The Need for Change

Today's heart valve replacement options fall into two categories: mechanical valves, which require lifelong anticoagulation and lifestyle adjustments, and tissue valves, which don't last beyond 10 to 15 years. Neither is

ideal, particularly for children with congenital heart disease who may face three or more open-heart surgeries before adulthood.

"A child may require surgery every two to three years just to keep pace with their growth," said White. "It's traumatic for families, costly for health systems, and inaccessible for much of the world."

White believes the regenerative approach could make single-surgery solutions possible. This would represent a major leap forward in both care and equity. "If we can implant a small valve that regenerates and grows with the child, it's one and done," he said. "That's life-changing."

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From Scaffold to Living Valve

Heart Biotech's solution is a ready-to-use, cell-free scaffold. Once implanted, it attracts local stem cells and triggers the regrowth of a new, living heart valve. Unlike competitors that rely on electrospinning or *ex vivo* cell seeding, Heart Biotech utilizes a proprietary jet-spraying method that produces a scaffold with heterogeneous fiber sizes that better mimics natural elastin and collagen.

"That biomimicry is the difference," said White. "It attracts the right cells, in the right sequence, and enables them

to differentiate into all the tissues that form a valve."

In 2023, the company published six-month preclinical data in *Nature*, demonstrating the regrowth of not only structural tissue but also nerve tissue, blood vessels, and adipose tissue.

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Momentum and Milestones

Heart Biotech is preparing for a regulated GLP animal study to validate the technology under conditions that mimic human use. The team has finalized its manufacturing processes and is targeting first-in-human trials in 2028. The company is also pursuing Breakthrough Device Designation with the FDA.

Recent milestones include:

- Securing additional funding from high-net-worth individuals, including the company's first SAFE agreement
- High level of activity, including due diligence, with venture capital firms and family offices from Europe, the U.S., and the Middle East

- A partnership with **BMG Financial Group** for representation in Saudi Arabia
- Application for EIS Advance Assurance
- Simplification of company structure through CARTA

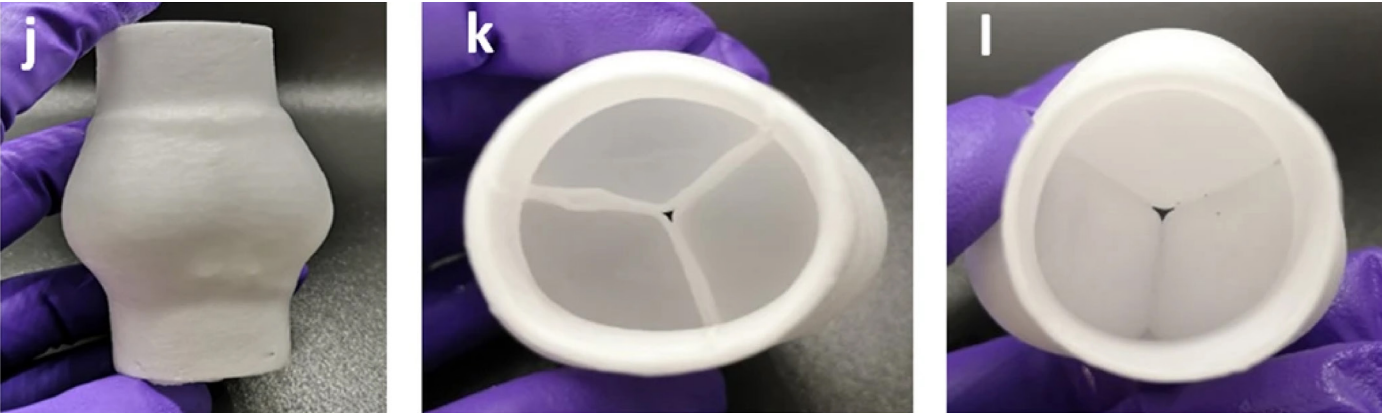
Heart Biotech is currently raising a \$15 million Series A round, which will fund completion of the GLP study and support regulatory engagement. The team has already raised \$5 million in equity and secured \$2 million in UKRI grants.

A Market-Defining Opportunity

According to LSI data, Tetralogy of Fallot procedures, many of which include pulmonary valve replacement, are among the fastest-growing congenital heart defect surgeries performed globally, expected to reach 70,400 procedures by 2029. Heart Biotech is initially targeting pulmonary valve replacement in adult Ross patients and pediatric congenital heart patients, representing a \$1.6 billion beachhead within a broader \$37 billion global market that includes heart valves, vascular grafts, and cardiac patches.

What's Next

As Heart Biotech continues advancing toward the clinic, White remains focused on execution, not hype. "We're building something the world has never seen," he said. "But we're doing it by standing on the shoulders of three decades of work and listening to what nature already knows how to do." **LSI**



Source: Heart Biotech