Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Imricor Medical Systems

By TIM BOREHAM

ASX code: IMR

Share price: 29.5 cents

Market cap: $44.6 million

Shares on issue: 151,347,625 (Chess Depositary Interests, or CDIs)

Founder, chair and chief executive officer: Steve Wedan

Board: Mr Wedan (chair), Mark Tibbles (deputy chair), Anita Messal, Peter McGregor

Financials (June half 2022): customer revenue $US538,000 ($A857,400) (up 47%), net loss $9.77 million (previously a $9.96 million deficit), cash balance $US9.1 million***** (down 41%). The company subsequently raised $2.92 million in a placement in mid-September

Identifiable major shareholders: Blackrock Investment 7.8%, Warren G Herreid 7.1%, Saville Capital 6.3%, Siemens Medical Solutions 5.5%, Regal Funds 4.7% Mark Tibbles 3.2%, Steve Wedan 3.03%.

The brightest innovations in medical science usually stem from a mix of serendipity, perspicacity and being in the right place at the right time.

In the case of American electrical engineer and Imricor founder Steve Wedan, a series of casual conversations convinced him of the need for heart procedure catheters that could be guided by magnetic resonance imaging (MRI), rather than traditional x-ray fluoroscopy.

Mr Wedan was working for GE Medical Systems designing MRI scanners and ultrasounds and heard about unsuccessful attempts by the heart company majors to design MRI-compatible catheters.

He started his own consultancy which led him to the esteemed Johns Hopkins Hospital in Maryland, where doctors asked him for help with projects they had been struggling with, including MRI-friendly probes.

“I did some due diligence to find out whether this was a tech in search of a medical application, or a real medical need that needed a technological solution,” he says. “I was convinced it was the latter.”

At the heart of the problem (literally) is the poor success rates with cardiac ablation procedures. The heart is invisible to x-rays, without potentially toxic dyes, and by the 1990s doctors could see the limitations of x-ray guided ablations, notably the cumulative radiation exposure (given patients are living longer).

The MRI-guided procedure is called interventional cardiac magnetic resonance (ICMR) imaging.

“We are not creating a new therapy, we are simply making the devices that are MRI compatible,” Mr Wedan says.

In a flutter

Cardiac ablation addresses the common problem of heart arrhythmia, or irregular heartbeat. This can be manifested in atrial fibrillation or atrial flutter, or Wolff-Parkinson-White syndrome and other tachycardias (rapid heartbeat).

Atrial fibrillation and atrial flutter account for 39 percent and 23 percent of all ablation procedures, respectively.

Cardiac ablation uses heat or cold energy to create tiny scars in the heart to block irregular electric signals and restore normal heartbeat.

A catheter is popped up a vein and delivers the electric impulses to destroy the abnormal tissue.

The process is carried out by electro-physiologists (specially trained cardiologists).

“There’s a really big need in interventional cardiology, electrophysiology and ablation for better visualization to specialize treatment for each patient,” Mr Wedan says.

“This will give the doctors a procedural endpoint so they can verify the therapy [and ensure] the patient will go home with a first-time success rate.”

Getting started

Mr Wedan founded Imricor in 2006, with an initial focus on ablation of ventricular tachycardia (or VT, more on that below).

The company is based in Burnsville, Minnesota, where it has its manufacturing and carries out research and development.

Imricor listed on the ASX on August 30, 2019, having raised $13 million at 83 cents apiece.

In 2011, the first human ICMR procedure was carried out at Germany's Leipzig Heart Centre.

In 2012, Imricor licenced its technology to Dutch tech giant Koninklijke Philips, and in 2018, the company inked its first contract with the Dresden Heart Centre.

Mr Weden is Imricor's founder, chair, president and CEO, which means the buck stops very much with him.

Imricor, by the way, is listed on the ASX because the company latched on to a US roadshow pitching the bourse as an alternative to venture capital.

"The ASX was a perfect niche for a stage of the company we were at," Mr Wedan says.

Ablation proliferation

Imricor's mainstay product is its Vision-MR Ablation Catheter, which is designed to look, feel and function like a traditional ablation catheter.

The European Union approved the device for atrial flutter in 2020, while also green-lighting the Vision-MR Dispersive Electrode. This gizmo minimizes eddy currents induced on the device's conductive pads during MRI scanning.

Then there's Imricor's Advantage-MR EP (electro-physiology) recorder/stimulation system, which is the hardware that enables the catheters to be deployed. This device was approved earlier in Europe, in 2016.

Imricor's devices are used at 15 European sites, including Germany's Helios Hospital Berlin-Buch, Berlin's German Heart Centre, the Henry Dunant Hospital Centre in Greece and Rome's Policlinico Casilino.

There's also a pipeline of further German, Dutch and Swiss centres.

In the US, the company has filed an application to the Food and Drug Administration for a trial, also for type one atrial flutter.

VT = Very Tricky

Imricor is targeting an expanded indication for ventricular tachycardia (VT) in Europe and has applied to carry out a 64-patient trial to support a marketing application.

The company hopes to kick off the trial by the end of 2022, with assent targeted in 2023 and a launch in early 2024.

One problem with our physiology is that the left side of the heart is hard to access, so God gets D-minus for architecture on that front. Imricor is working on a steerable sheath and trans-septal needle to access the left side of the heart.

“VT is a growing indication,” Mr Wedan says. “Doctors report a wave of VT patients starting to come because patients with planted defibrillators are alive when a couple of decades ago they would [have died earlier].

“It’s a very difficult procedure and one for which MRI will offer substantial and immediate benefits.”

Finances and performance

Imricor clocked up a record $US136,000 ($A217,000) of consumables revenue in the three months to June 30, 2022, almost double year-on-year and 46 percent up on the March 2022 quarter.

Over the June half-year, the company recorded $US229,000 of consumables revenue and $US250,000 of equipment revenue. The total June quarter revenue of $US250,000 reflects limited European sales after the product was relaunched post-pandemic.

“We have seen the last major effects of the pandemic drop away,” Mr Wedan says. “We expect very robust sales in the third [September] quarter and more in the fourth quarter.”

In September 2021, the company raised $16.5 million in a placement, followed by a $1 million share purchase plan. In September this year, the company followed up with a $2.92 million placement to existing investors, at 38 cents apiece.

Meanwhile, management is on the job with the scalpel, excising $US10 million of costs from the current-year budget. Costed at $US1.5 million, the vaunted European VT trial is Imricor’s main expense.

Even if the US application is approved, any trial there is likely to be delayed until European revenues flow in earnest.

Imricor shares peaked at $2.78 on October 30, 2020, but it’s been a downhill trajectory since then, bottoming at 14 cents on June 24 this year.

The company dead-batted an ASX query as to why its share price zoomed from 29 cents on August 10, to 49 cents on August 12.

Sizing up the revenue potential

In Europe, there are currently about 1,000 ICMR laboratories carrying out an average of 70 atrial flutter procedures a year, each. The company estimates that snaring only five percent of this market would generate revenue of $US12 million, at an average $US3,500 per procedure.

Adding the indications of VT and atrial fibrillation would greatly expand the market size.

The expected US market is about 1,100 sites, but probably double European revenue because of superior reimbursement.

Imricor's revenue would derive from the 'razor/razor blade' model, by which clinics buy the recorder/stimulator device, with single-use catheters and electrodes purchased for each new patient.

Mr Wedan describes the cost as similar to that of a standard ablation catheter.

"The value proposition is that if we can get the procedure right in one go instead of two or three, the overall price per patient goes down."

Mr Wedan says medical device adoption is always gradual, but when clinicians are convinced they usually don't waver.

"Just as it's hard to change to [a new device], it's hard to change from."

Getting cosy

Imricor has more alliances than a NATO war room, including a global development agreement with global MRI hardware vendors Siemens and a distribution agreement with Philips.

Imricor has development or distribution agreements with Nordic Neurolab AS, which makes MRI-compatible in-room monitors, as well as a strategic investment in Mirtle Medical LLC, which makes MRI-compatible 12-lead electro-cardiogram (ECG) systems.

In 2021, the company entered a compact with the Sydney based Regional Health Care Group to facilitate local Therapeutic Goods Administration. And – hey bro - the catheter is already approved in New Zealand.

Of course, the Aussie market is small, but Mr Wedan says "it's good to be a relevant local story for investors."

Some readers might be wondering why the big heart device companies have not cracked the MRI-compatible nut.

"There wasn't a great understanding of the electro-magnetic fields in MRI with the engineers who make pacemakers," Mr Wedan says.

Dr Boreham's diagnosis:

Imricor is playing in a global catheter ablation market worth $US5.5 billion and growing at a compound rate of just over eight percent a year.

"Only Imricor makes MRI-compatible devices so we capture 100 percent of the market," Mr Wedan says.

The growth drivers include a higher incidence of heart disease, a shift to minimally invasive treatments and the cost effectiveness of the procedure.

On a more negative company-specific note, Imricor is reliant on third-party equipment while obsolescence is an ever-present threat. It also has a heavy cash-burn.

Nonetheless, Mr Wedan says Imricor's "heavy lifting" is paying off.

"We are really changing the world of interventional cardiology and fulfilling a dream we have had for 16 years," he says.

"For many of us [at the company] it will be the most significant thing we do in our career. We have the chance to do what no-one has been able to do and add real tangible value to healthcare and patients around the world."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But at least he knows the difference between ablations and ablutions, so scrubs up well in that regard