Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: EBR Systems Inc

By TIM BOREHAM

ASX Code: EBR

Share price: $1.365; **Shares on issue** (CDIs): 372,896,324; **Market cap:** $509.0 million

CEO: John McCutcheon

Board: Allan Will (executive chair), Mr McCutcheon, Dr Christopher Nave, Trevor Moody, Dr Bronwyn Evans, Dr David Steinhaus, Karen Drexler

Financials (calendar 2024): income nil, net loss $US41.2 million (previous loss $US32.7 million), cash balance $US64.5 million (at December 31, 2024)

*$US1.00 = 62 Australian cents

Major identifiable shareholders: Hostplus 11.5%, HESTA 8.6%, Brandon Capital (partners and clients) 5.6%, MH Carnegie Funds 11.0%, Split Rock Partners LP 7.2%

The US Food and Drug Administration might be in a mess, but a slew of ASX biotechs can't complain that the agency's approval process has stalled.

This month, the FDA approved Artrya's arterial plaque detection tool, Salix Coronary Anatomy and then gave the nod to Orthocell's nerve repair device, Remplir.

The private Headsafe MFG won assent for its wearable concussion headset.

Now, EBR Systems joins the happy list after the FDA brandished the 'approved' stamp on the company's novel wireless pacemaker device, Wise.

Wise is the only leadless left ventricular endocardial pacing device and the only one able to deliver cardiac resynchronization therapy (CRT).

“It’s a spectacular day for us and for shareholders,” Mr McCutcheon said.

“It changes us from a clinical company [to one] with a commercial footing where it’s more about execution and growth.”

Investors were less chuffed and wiped 22 percent off the stock, apparently because of profit taking on the back of the company’s stellar share run.

EBR plans to sell to selected heart surgeons by the end of the year, in a $US3.6 billion addressable market.

To date, EBR has spent $US340 million to develop Wise.

Three Wise guys

What happens when an electro-physiologist, an ultrasound scientist and pacemaker engineer walk into a bar?

You don’t get a joke, but a better way to undergo cardiac resynchronization therapy (CRT) by accessing the left ventricle and removing annoying leads that are prone to failure.

The trio, Dr Debra Echt, Dr Axel Brisken and Richard Riley founded the Silicon Valley based EBR in 2003.

Bletchley Park cryptologists would pick up that ‘EBR’ combines their initials.

Dr Echt saw a problem with leads and thought there was a better way to defibrillate (reduce dangerous rapid heartbeat) the heart.

With a background in sales and marketing in the heart device sector, Mr McCutcheon joined EBR in 2019.

EBR listed on the ASX on November 24, 2021, having raised $110 million at $1.08 apiece.

In May 2023, EBR reported its 183-patient, pivotal study for its Wise device met its primary safety and efficacy endpoints, for patients with acute and chronic lead failures and high-risk upgrades.

European authorities approved the device in October 2015, but regulatory upheaval there meant that selling initially in the US was more attractive.

More than 500 patients have been embedded with Wise to date, with the first Australian patient implanted in February 2018.

This use relates to clinical trials and special access arrangements.

The heart of the matter

Wise stands for ‘wireless stimulation endocardially’ – but we all knew that already.

CRT involves inserting electrodes in the left and right ventricles of the heart, as well as on occasion the right atrium, to treat heart failure by coordinating the function of the left and right ventricles via a pacemaker.

If the right ventricle contracts before the left one, desynchrony occurs and the ticker does not pump blood adequately.

CRT is a subset of the cardiac rhythm management sector, which includes bradycardia pacing (for slow heart beats) and defibrillations via high voltage leads added to the pacemaker.

Pacemakers have saved many lives, but the trouble is about four percent of the embedded leads fail every year. The longer the pacemaker is in there, the higher the chance of failure.

One reason the left ventricle is trickier is because it circulates arterial blood straight to the brain. The right side (venous blood) circulates through the lungs and is less prone to clotting. To avoid clots, the left-side leads are currently placed in the surrounding coronary sinus, with stimulation occurring outside the chamber.

Being wireless, Wise obviates this problem.

A very handy grain of ‘rice’

The size of a grain of cooked rice – and we’re talking Jasmine rather than the fatter Arborio – Wise, powered by a subcutaneous battery, is embedded in the heart to provide left ventricle pacing stimulation.

A transmitter picks up the groove of the right ventricle and sends a signal to the Wise electrode, which converts ultrasound energy to electrical energy to stimulate the left ventricle.

The transmitter sits between the ribs and is flush to the skin, so it is unobtrusive and not noticeable to the patient.

What’s the target market?

Wise provides the only way for patients to upgrade from leadless pacemakers to CRT.

To be clear, other wireless pacemakers have been developed, but they cater for the right ventricle. Wise is designed to be used alongside them.

Medtronic was the first five years ago with Micra and then Abbott followed with Aveir. Boston Scientific awaits approval of a third device, Empower. These right-side devices pace for non-heart failure arrythmias such as bradycardia (slow heartbeat).

“In these cases, the arrhythmias are treated in the right ventricle. But with heart failure, the left ventricle needs to be included for the condition to be treated effectively.”

Use strictly as directed

The FDA has bestowed broad indications for Wise, the first being that the patients are at least 22 years old and have an implanted right ventricular pacing system. The allowed uses cover four sectors that comprise the $US3.6 billion market. They are high-risk leadless upgrades, high-risk conventional upgrades and acute and chronic lead failure.

High-risk upgrades mean the surgeons have attempted to place a lead in the coronary sinus to access the left ventricle. Or the procedure has been deemed to be too dangerous in the first place.

Another scenario is when a patient with a lead-based pacemaker progresses to needing CRT, but a left ventricle lead would be too risky. About 30 percent of this cohort will require CRT within four years.

In these cases, the patient might be re-installed with a leadless right ventricle device, in conjunction with Wise. In other cases, leads may have been removed because of infection and re-installing them risks further infection.

The biggest single opportunity lies with chronic lead failures, a $US1.45 billion a year market.

Finances and performance

EBR lost just under $US11 million in the fourth (December 2024) quarter, with a full year loss of $US41.2 million compared with a $US32.7 million loss previously.

Research and development costs came in at $US6.65 million. But they trended down to $US601,300 in the December quarter from $US2.5 million in the March stanza, because the company has been capitalizing its pre-launch inventory purchases.

But it’s swings and roundabouts, with product manufacturing and operating costs up from $US493,000 in the March quarter to $US2.3 million in the December quarter (for a year’s total of $US4.25 million).

In October last year EBR raised $50 million in a placement and share purchase plan (SPP), at 82 cents apiece. In mid-2023 the company raised $35 million, also in a placement and SPP, at 91 cents apiece.

At the time, EBR also drew $US20 million on a $US50 million deal signed with Runway Growth Capital in mid-2022. The first $US20 was drawn at the signing of the deal.

With $US66 million ($105 million) of cash on hand, EBR says it is adequately funded for "initial" commercialization.

Over the last 12 months, EBR shares have ranged between 83 cents (September last year) and an all-time high of just over $2.00 (late March this year). Despite the post-approval pull-back – and an attempted rebound fizzled out - the stock has gained about 64 percent over the last year.

EBR has a bevy of big-ticket names on the register, including industrialist Mark Carnegie, Brandon Capital and industry super funds HESTA, Hostplus and Australian Super.

Since last October, EBR has been exempt from ASX reporting requirements and falls under US reporting rules.

Rearing to go

EBR has been building inventory and amassing a small direct sales force.

For those worried about tariffs, EBR recently took out an 11-year lease on an expanded, 4,750 square metre production facility at Santa Clara, in the heart of Silicon Valley.

Given the cardiac community is small, EBR will sell directly in the US initially, but is amenable to using distributors elsewhere.

Mr McCutcheon cautions investors not to expect a "rocket-ship take-off": initial uptake could be slow, as clinicians familiarize themselves with the product.

The company sees first use by 20 to 40 heart centres, with first adopters likely to use them for 10 to 25 percent of procedures.

He says EBR has a "clear path" to US reimbursement, expected by October this year.

The company has modelled per-procedure public and private reimbursement at $US45,000, but Mr McCutcheon says: "we certainly want to get more than that".

EBR has been accepted into the "new technology add-on payment" pathway and other exotic reimbursement conduits.

Mr McCutcheon adds that pacemakers were becoming commoditized until Medtronic entered the market with Micra five years ago.

"Now, it is the most dynamic and fastest growing part of the market, because of wireless devices," he says.

"That's a proxy for our future and how it will parlay into our success."

Dr Boreham's diagnosis:

As Mr McCutcheon notes, EBR has now grown-up and reached the life sciences equivalent of adulthood.

But he well knows that commercial-stage companies can have growing pains and stresses the rollout will be measured enough to pick up problems before they become big ones.

"I've done a lot of new technology launches, but as smart as we think we are, there's always something we didn't learn."

In 2021 alone, the FDA ordered recalls on certain Medtronic and Abbott pacemakers and Medtronic defibrillators, owing to premature battery depletion.

Another commercial reality is that major product rollouts involve buckets of money.

While EBR has $105 million, broker Bell Potter expects the company will raise a similar amount this year to complete US commercialization in the US and attack other markets.

Bell Potter also forecasts EBR will post a $US48 million loss this year and deficits of $US52 million and $US42 million in 2026 and 2027.

Still, with its FDA certificate safely in its corporate paws, EBR becomes a de-risked company more befitting its $500 million-plus market valuation.

One oddity of it all is why the wise guys at the heart device giants haven't devised their own left ventricle devices.

The simple reason is that's it's hard and when you are making a lot of money from what you are currently doing, you just keep doing it.

"We are going to own our space for some time, we don't see any threats on the horizon," he says.

"Everything looks like it is going our way."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He sees no threats on the horizon and everything is going his way, not that he earns that much from doing what he's doing.