



Biotech Daily

Friday June 19, 2026

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: EBR Systems Inc

By TIM BOREHAM

ASX Code: EBR

Share price: 38 cents

Shares on issue (CDIs): 638,492,410

Market cap: \$242.6 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 (March quarter 2026*): sales revenue \$US2.32 million (\$A3.39 million), cash outflows \$US20.25 million, cash and equivalents \$US33.5 million, prior to a \$A150 million capital raise

Major identifiable shareholders: Hostplus 8.7%, Hesta 6.2%, Argo 4.3%, Split Rock Partners 3.1%, Carnegie Group 4.6%, Regal 2.0%.

As Frank Sinatra crooned, if you can make it in New York, you can make it anywhere.

For heart device maker, EBR Systems, the company's monumental moment happened in the Windy City, rather than the Big Apple.

To be precise: at April's Heart Rhythm Society jamboree in Chicago, attended by 10,000 ticker professionals.

EBR sponsored a lunch symposium, at which expert clinicians presented on how to use EBR's Wise device.

"It was standing room only," EBR CEO John McCutcheon says.

"There were probably 20 other activities and seminars that people could choose from ... and we still managed to make a splash in that big pond".

The heartening response – excuse the pun – comes as EBR traverses a key stanza of its US rollout of Wise, its wireless pacemaker for cardiac re-synchronization therapy (CRT).

Roughly six months into the staged commercialization, Mr McCutcheon is thrilled by the pace of surgeon and hospital adoption that's been underpinned by favorable reimbursement.

Meanwhile the company has ameliorated balance sheet concerns with a chunky \$150 million capital raising (see 'Finances and performance').

Wise up

Wise stands for 'wireless stimulation endo-cardially'.

Wise is the world's only wireless, endo-cardial (inside the heart) pacing system, for stimulating the heart's left ventricle.

"This has long been a goal of cardiac pacing companies, since internal stimulation of the left ventricle is thought to be a potentially superior, more anatomically correct pacing location," the company says.

Wise is for patients whose left and right ventricles aren't beating in synchronization.

"We put in a very small implant the size of a grain of rice, inside the left ventricle," Mr McCutcheon says. "That paces it in synchrony with the right ventricle and this reverses the symptoms and the progress of heart failure."

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 unit is powered by a sub-cutaneous battery.

CRT involves inserting electrodes in the left and right ventricles of the heart, to coordinate the function of the left and right ventricles via a pacemaker.

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, for erratic heart beats.

The trouble with pacemakers is that the longer they are inserted, the higher the chance of failure.

Left ventricle blood flow is thicker and thus prone to clotting.

To avoid being gummed up, the left-side leads are currently placed in the surrounding coronary sinus.

Being wireless, Wise obviates this problem.

The US Food and Drug Administration has approved Wise for high-risk leadless upgrades, high-risk conventional upgrades and acute and chronic lead failure (the biggest market).

In other cases, leads may have been removed because of infection and re-installing them risks further infection.

Moving to the beat

EBR was formed in Silicon Valley in 2003, by electro-physiologist Dr Debra Echt, ultrasound scientist Dr Axel Briskin and pacemaker engineer Richard Riley.

(‘EBR’ derives from their initials).

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 Solve study 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 EBR is yet to sell there in earnest.

EBR’s breakthrough moment came in April last year, when the FDA green-lighted the device.

In the three months to December 31, 2025, EBR initiated a limited market release to “strategically selected centres”.

In mid-April, the local Therapeutic Goods Administration granted the device priority review, opening an accelerated approval pathway.

Surgeons implanted the first Australian patient in February 2018, under a special excess arrangement.

US rollout is more than a sales pitch

EBR has opted to build a direct sales force, rather than using distributors.

“Medtech is a high-touch business,” Mr McCutcheon says. “We want to control our own destiny and have the best experience for the customer and for the doctor.”

The EBR salespeople are trained medicos.

The sales process starts with one-on-one contact with the physician.

“We don’t do marketing – it’s all person-to-person,” Mr McCutcheon says.

“Once the doctor or the electro-physiologist convinces us that they’re sincere and serious ... we will move the process forward.

“We’re not interested in somebody who says: ‘I heard [Wise] is really neat, I would like to try one.’”

The physicians need to put aside a day for training – and time is money. The company pays for expenses, but not their time.

“There’s an adoption curve to every technology, with the early adopters and then the fast followers,” Mr McCutcheon says.

“You have to find the [physicians] who might believe in it even before you do”.

Then there’s the challenge of being introduced to hospital administrators to secure a contract.

“Every hospital is unique, with different levels of bureaucracy and degrees of difficulty in [adopting] new technologies”.

Numbers are ticking up

In the March 2026 quarter, US clinicians implanted 41 patients with the device, taking the tally to 71.

The company has sealed 16 purchase agreements with 22 doctors trained (taking the total to 52).

The company said the uptake in use reflected the “growing experience of trained physicians and the increasing readiness of participating hospitals”.

“With [US] Medicare reimbursement now in place across inpatient and outpatient settings, our focus remains on disciplined execution, high-quality patient outcomes and building the infrastructure required to support the next phase of commercial growth.”

In May, EBR inked a purchasing agreement with Advocate Health, the third biggest US not-for-profit integrated health system, covering 69 hospitals in Alabama, Georgia, Illinois, Indiana, Michigan, North Carolina, South Carolina and Wisconsin.

Two days later the company sealed a three-year deal with Christus Health, the ninth biggest hospital network in the US covering 66 facilities.

EBR expects the signings to lead to more wins across the US not-for-profit and 'faith based' health system.

Mr McCutcheon won't disclose the company's expected surgical volumes, but he's comfortable with analyst estimates.

As a guide, Bell Potter pencils in 1,300 implants in 2027.

Finances and performance

Commercializing a major medical device involves large licks of money - and EBR has been burning through it, despite raising \$76 million after Wise was approved last year.

But not to worry: on June 4, EBR launched a monster \$150 million capital raising.

The effort consists of a \$64.4 million, fully underwritten placement; and a further \$85.6 million via a non-renounceable one-for-two rights offer.

The \$35.7 million retail component opened on June 11 and closes on June 22.

The raising is struck at 38 cents per share, a 19.1 percent discount to the previous 'frozen' closing price.

EBR chalked up \$US2.32 million of sales revenue in the March (first) quarter, compared with \$US1.62 million for all of 2025.

The company had cash outflows of \$US20.3 million during the quarter, leaving cash and equivalents of \$US33.5 million. Post-raising the company will have around \$A200 million in the bank.

On March 12, shareholders approved a reverse 1-for-10 US stock split. EBR's ASX-listed Chess Depositary Interests (CDIs) were not consolidated, but CDI-to-common share conversion ratio changed from 1:1 to 10:1.

So, nothing to see here - move on!

Over the last 12 months, EBR shares have ticked up to \$1.47 (mid-October last year) and arrested to a post-raising low of 36 cents on June 11 this year.

The stock peaked at an all-time high of \$1.99 in mid-March last year.

Size of the prize

The company estimates the US total addressable market at \$US5.8 billion a year, including \$US2.7 billion from previously untreatable chronic and acute cases and \$US1.4 billion from high-risk upgrades.

Around 10 percent of all heart failure patients in the US meet the criteria for cardiac resynchronization therapy.

Post approval, the Centers for Medicare & Medicaid Services (CMS) granting favorable New Technology Add-On Payment reimbursement for inpatient use.

It also bestowed Transitional Pass-Through reimbursement for outpatients, both effective from 1 October 2025.

The upshot is that in both scenarios Wise has a selling price of \$US63,300 per procedure.

Where's the competition?

The short answer is nowhere.

"I don't see it coming from anywhere and in our industry you can't [develop a new device] by stealth," Mr McCutcheon says.

"When somebody has an early idea, first you hear a rumor.

"Then you see an animal study or an early scientific paper, and then first-in-human trials. It's a decade-long process and no one can come out of the ether and surprise you."

It's a moot point as to why heart device giants such as Medtronic dropped the ball on the left ventricle stuff.

We guess they were making enough money with their extant products.

Mr McCutcheon cites other potential applications for Wise, notably congenital heart issues.

"We're getting a lot of interest from clinicians about that", he says.

"Sometimes patients are born with one ventricle, or their great arteries are juxtaposed and they have these rhythm issues."

Wise could be used in paediatric cases because the arteries are so small.

"We'll probably pursue that at some point," he says.

"We also have to stay focused on the main mission [of US commercialization]."

Dr Boreham's diagnosis:

Investors should expect years of heavy losses until the return on US investment kicks in.

Bell Potter estimates a \$US59.7 deficit in calendar 2026, abating to a \$US21.3 million loss in 2028.

Having launched multiple medical technology devices, Mr McCutcheon says it helps to stay humble.

"You never know exactly how they're going to go, because each one is unique and different factors dictate the rate of adoption," he says.

"But I've been really thrilled with our progress. The cases are going well, the doctors are really happy, and the patients are doing great."

"We're getting repeat business and we're getting those contracts signed."

Mr McCutcheon says he has feedback from doctors who previously could do nothing for the patient.

"It's very gratifying," he says.

"When they can treat a patient that they never could before these procedures, there are literally high fives and tears with the family."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has managed to stay humble and is constantly reminded he has much to be modest about.