Biotech Daily

Friday September 18, 2026

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Echo IQ

By TIM BOREHAM

ASX code: EIQ

Share price: 77.5 cents

Shares on issue: 740,874,779

Market cap: $574.2 million

Chief executive officer: Dustin Haines

Board: Andrew Grover (executive chair), Steven Formica, Stephen Picton, Ken Nelson, Scott Wilkin

Financials (year to June 30, 2026): operating revenue $91,656 (down 9.6%), loss of $18.56 million ($13.26 million deficit previously), cash of $8.71 million (up 31%, ahead of $110 million equity raising in July 2026)

Identifiable major shareholders: A22 Pty Ltd 4.4%, Stevsand Investment Pty Ltd (Steven Forman family) 4.18%, Brian Glynn 2%

'Time is money' is an – er - timeless aphorism often associated with exorbitant airport parking and plumbers who charge by the hour and thus are happy to stop for a cup of tea and a yak.

The concept is also highly apt for the medical device (and drug) game, as shown by the fate of shooting star Echo IQ. Last week, the US Food and Drug Administration rejected the heart device play's clearance submission for its heart failure detection device, Echosolv HF.

Echo IQ filed under the easier 510(k) predicate device route, but sadly the agency decreed that the algorithm driven tool was “not substantially equivalent” to anything else.

So, the company wins points for inventiveness, but that didn’t stop investors from smashing the share price.

The knockback does not appear to be the end of the story. Echo IQ is mulling its next move and yesterday confirmed it had a few levers to pull (see below).

But the ‘time is money’ equation enters the picture because whatever course the company decides to take, it is missing out on commercial sales that were tipped to start as early as next year.

At best, this timeline should be wound back by at least 12 months to two years.

Originally, the company expected approval by late 2024, so time slippages are the order of the day.

What’s all the fuss about?

Echo IQ focuses on using artificial intelligence to reduce complexities in diagnosing cardiovascular disease.

The company already has a commercial product with Echosolv AS (aortic stenosis), which detects a narrowing of aortic valves, providing a more accurate and earlier diagnosis of the common condition.

Caused by calcification, aortic stenosis can be treated only with replacement valves.

Unlike current methods, Echo IQ doesn’t rely on blood obstruction measurement to detect the condition, rather its algorithms interpret electro-cardio-grams (ECGs).

About 30 to 50 percent of patients are mis-diagnosed. In the case of women, the fail rate is more like two thirds, because the guidelines don’t consider that female hearts and arteries are smaller.

Electrocardiograms (ECGs) are widely available and cost effective. But cardiologists are often looking for multiple conditions at once. As cardiac conditions have similar symptoms, this leads to under-diagnosis. The FDA approved Echosolv AS in October 2024.

This gave rise to (false) hopes that Echosolv HF approval would be a slam-dunk (or in deference to last week’s US gridiron visitors, a touchdown).

Echosolv HF addresses a much broader market and was considered the company maker.

Echo IQ estimates the US aortic stenosis market at 1.5 million sufferers, compared with 6.7 million for heart failure.

The story to date

Echo IQ evolved from the National Echo Database of Australia (NEDA), the world's biggest repository of ECG images.

The company was founded by NEDA's founders, Dr Geoff Strange and Prof David Playford.

Echo IQ listed in March 2021 via a reverse merger with the oddly-monikered AI company Houston We Have.

Houston We Have provided data analytics to Australian health insurance funds but failed to lift off.

In 2021, healthcare giant Edwards Lifesciences agreed to fund the company's aortic stenosis clinical trials, which compared Echosolv with the ability of clinicians to detect the malady manually across 9,189 electro-cardio-grams (ECGs).

The clever Echosolv AS detected all 376 aortic stenosis cases, compared with 218 for the human appraisers

In January 2025, Dustin Haines took the reins as CEO.

Mr Haines was Gilead Sciences' general manager for Asia, the Middle East, Turkey and Russia.

Before that, he was chief commercial officer for the then ASX-listed wound-healing house Next Science.

In mid-August this year, radiology imaging giant Pro Medicus invested $10 million in Echo IQ, to enhance its fledgling cardiology offering.

Pro Medicus can invest up to $10 million more.

Pro Medicus, of course also invested $10 million in tearaway lung imaging house 4D Medical.

To date, Echosolv AS has been used by Boston's Beth Israel Deaconess Medical Centre, a Harvard teaching hospital. The Mount Sinai Health System also has signed up.

Lodged with the FDA in December last year, the Echosolv HF submission was supported by an independent validation study at the Mayo Clinic, which analyzed 17,000 ECGs.

Echosolv HF showed a 99.5 percent ability to detect patients with heart failure and a 91.1 percent ability to rule out the condition.

Mayo was the most likely first commercial customer for Echosolv HF and had dibs on redistributing and reselling the product in the US.

What now?

Mr Haines said he was shocked and “deeply disappointed” to receive the FDA rejection email at 5 pm on Friday, September 4 – just ahead of the US Labor Day long weekend.

“There aren’t enough curse words in the English language to cover what I said on Friday night,” he told an investor webinar last week.

While he described the knock-back as “incredibly frustrating”, he stressed it was a “setback and delay” rather than a “catastrophic event”.

The FDA’s concerns boiled down to statistical analysis of data, rather than safety worries.

Where to from here?

In yesterday’s update, Echo IQ said it still had a “clear path forward” to FDA clearance, which “could potentially be achieved over the coming quarters”.

The company stresses the FDA raised no concerns about the underlying technology or core functionality of Echosolv HF.

The agency’s concerns related merely to “aspects of statistical analysis supporting clinical validation”. The company does not specify a 510(k) submission. Other options include an appeal through established FDA channels, or review by the FDA Ombudsman.

Naturally, the first port of call is a cup of tea with the FDA reviewers, to glean their exact concerns.

Last week, Mr Haines said each option came with its own “pros and cons”. At least rectification is unlikely to require a fresh clinical program, which would be costly and time consuming.

Mr Haines says the company could re-analyze the Mayo data if required, “in weeks if not days”. “510(k) [rejection] is rarely a no. It is ‘we would like you to resubmit, and we will continue the process’,” Mr Haines said.

Other indications

After a regulatory or clinical knockback, the narrative shifts to other indications a company might pursue.

Echo IQ makes it clear that getting Echosolv HF over the line remains its priority. But other work is bubbling away in the background.

The company cites an interest in pulmonary hypertension, hypertrophic cardio-myopathy, mitral regurgitation and cardio-oncology.

The work is at an early stage.

In June this year, Echo IQ entered into a research collaboration with the Mayo Clinic, to evaluate using its artificial intelligence (A.I.) platform for cardiac risk stratification in cancer patients.

Mayo Clinic Arizona is currently carrying out the study.

The trial will assess the ability of Echo IQ's A.I. model to generate predictive heart-failure risk scores from routinely acquired ECG data, for patients undergoing cancer treatment.

Echo IQ and Mayo expect results by July 2027, after which they will be published in an esteemed peer-reviewed journal.

Finances and performance

At least Echo IQ is well cashed up to pursue Echosolv HF remediation or new indications.

At the end of July, the company had $105 million in the bank. Anticipating approval, in that month the company raised $110 million in an institutional placement, at $1.45 a pop (an 8.8 percent discount).

Ouch!

Chief financial officer Matthew Dodd says the company will continue to invest in research and development to develop new modalities.

Echo IQ generated modest operating revenue of $91,646 for the 12 months to June 30 2026, 9.6 percent lower than the previous year.

The company reports a cumulative 20,000 Echosolv AS analyses.

The company lost $18.56 million, compared with a previous $13.26 million deficit.

The company reports the initial $10 million Pro Medicus investment, by way of convertible notes, has not been drawn down.

Over the last 12 months, Echo IQ shares have fluttered between 17.5 cents in September last year and $1.75 on July 2 this year. On Wednesday last week the shares fell up to 65 percent after the FDA setback.

Ahead of the FDArmageddon, they had soared almost fourfold since the start of the year.

Naturally, Pro Medicus's investment piqued investor interest, but as it happens Pro Medicus hasn't picked the same winner as it did with 4D Medical.

Before the share slump, Echo IQ was elevated to the S&P/ASX300 index, effective from next Monday.

What the brokers sayeth

The consensus of healthcare analysts is that Echo IQ's FDA problems are fixable, but time is money …

Morgans says the rejection pushes back the company's "biggest near-term catalyst and revenue driver".

The firm notes the FDA rejection came close to the end of its allowable 270-day decision time frame, "leaving the agency no scope to seek further information and forcing a decision on what it had".

The firm retains a 'speculative buy' call but cuts its per-share valuation from $1.85 to $1.10.

Bell Potter is less sanguine, changing its speculative buy call to a sell and slashing its valuation from $1.75 a share to 30 cents.

Bell Potter says that Echo IQ possibly could access "further confirmatory evidence" from the Mayo Clinic validation study.

The broking firm posits the statistical analysis problems related to the algorithm picking up non-cardiac mortality risks in older patients.

But Bell Potter says at this stage there are too many questions and too few answers.

"One thing for certain is that resolution will not be rapid," the firm says.

"If the solution were straight forward, the company would have said so and for this reason we expect many months, if not years, of delay."

Petra Capital analyst Tanu Jain says FDA rejection is "not necessarily terminal", with plenty of examples of companies gaining FDA clearance after addressing the agency's concerns.

But the firm moves from a 'hold' to a 'sell' call because – you guessed it – time is money.

Dr Boreham's diagnosis:

On an ominous note, Morgans notes that large heart device players such as GE Healthcare and Philips are developing "similar cardiac A.I. solutions".

So too is A.I.-focused ASX peer Artrya.

This means Echo IQ's first-mover advantage could erode – which just goes to show that … time is money.

The truth is investors jumped the gun on this one and the stock is unlikely to challenge its peak valuation of more than $1.1 billion any time soon.

While it might be easier to get a device over the regulatory line than a drug, who said there were guarantees?

Now, all management can do is to calmly work through the issues.

Meanwhile, cardiovascular disease remains the world's biggest killer - and a key reason is that diagnosis occurs far too late or not at all.

Echo IQ's US head Nick Lubbers says: "Smooth seas never made a skilled sailor".

Indeed, let's hope the company emerges from its FDA-induced sea sicknesses with a shipshape proposition for shell-shocked investors.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He's navigated a few stormy seas, but tries to keep his feet on dry land.