



Biotech Daily

Friday September 18, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX EVEN, BIOTECH UP: 4D MEDICAL UP 13%
- CURVEBEAM, IMMUTEP DOWN 16%**
- * **DR BOREHAM'S CRUCIBLE: ECHO IQ**
- * **BIOINTELECT OPENS \$8.5m VENTURER ROUND 2 ON MONDAY**
- * **MEMPHASYS INVIDO EUROPE \$674k FELIX CONTRACT**
- * **CURVEBEAM SHORTFALL RAISES \$1.75m; TOTAL \$7.36m**
- * **ADALTA: ORIBIOTECH \$168m CONTRACT 'VALIDATES OUR DECISION'**
- * **TISSUE REPAIR AGM 95% BACK ASX REMOVAL, BUY-BACK**
- * **AUSTCO 1.1m CEO CLAYTON ASTLES PERFORMANCE RIGHTS AGM**
- * **COCHLEAR APPOINTS PROF IAN MEREDITH DIRECTOR**

MARKET REPORT

The Australian stock market slipped 0.01 percent on Friday September 18, 2026, with the ASX200 down 1.2 points to 8731.2 points. Twenty-one of the Biotech Daily Top 40 companies were up, 11 fell and eight traded unchanged.

4D Medical was the best, up 51 cents or 13.4 percent to \$4.31, with 12.5 million shares traded. Botanix climbed 11.1 percent; Actinogen was up 9.6 percent; Artrya improved 8.2 percent; EBR was up 6.1 percent; Micro-X climbed 5.9 percent; Envizion and Lumos were up four percent or more; Avita, Clarity, Imricor, Resonance and Starpharma were up more than three percent; Clinuvel, Compumedics, Mesoblast and Telix rose more than two percent; Nanosonics and Prescient were up more than one percent; with Neuren, Polynovo and Pro Medicus up by less than one percent.

Curvebeam led the falls, down 0.5 cents or 15.63 percent to 2.7 cents, with 3.3 million shares traded, followed by Immutep down 0.7 cents 15.56 percent to 3.8 cents, with 103.75 million shares traded. Proteomics lost 7.1 percent; Optiscan was down 6.7 percent; Nova Eye fell 5.4 percent; Saluda was down 3.6 percent; Cyclopharm and Paradigm shed two percent or more; Alcidion, Cochlear, CSL and Medical Developments were down one percent or more; with Orthocell and Resmed down by less than one percent.

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 and 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, 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, which 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 FDA Armageddon, 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 that, 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.

BIOINTELECT

Biointellect says its \$8.5 million Venturer Round 2 funding opens on Monday September 21, and closes on October 16, 2026.

Biointellect said that its Biointellect Venturer was “Australia’s national incubator for infectious disease innovation, helping promising Australian scientific innovators accelerate their path from discovery to impact”.

The company said that the program combined “catalytic non-dilutive funding, commercialization expertise, strategic guidance, networks and tailored support to progress early-stage innovations towards commercial and investment readiness.

Last month, Biointellect said it would provide \$10.48 million to six Australian companies, including Ena Respiratory, working on infectious disease projects in its inaugural ‘Venturer’ program funding round (BD: Aug 31, 2026).

The company said at that time that it was an incubator established through a \$32.9 million Medical Research Future Fund grant from the Federal Government and that the funding would provide “research teams [with] the ability to advance their early-stage breakthroughs to commercial and investment readiness”.

Today, Biointellect co-founder Jennifer Herz told Biotech Daily that the total amount would be expended in three rounds with the third, a “top-up round”; and the milestone-based Biointellect Venturer program intended to make the companies sustainable in their own right, with a cap of \$5 million per company over the three rounds.

Biointellect said small and medium sized enterprises, research teams and innovators working on the prevention of infectious diseases were encouraged to apply for Round 2.

The company said prospective applicants, including those who applied in Round 1, should review the Round 2 funding guidelines and frequently asked questions before applying to confirm their eligibility and understand the application and assessment process.

For more information, go to: <https://www.biointellect.com/biointellect-venturer/>.

Biointellect said the Venturer program was hosting two online sessions, one an information session on September 24 and the second a grant writing workshop on September 30, to provide further information, an opportunity for questions and answers, and support and advice to help strengthen applications.

Biointellect is a private company.

MEMPHASYS

Memphasys says it has an EUR416,200 (\$A674,000) agreement with Invido Lab sro to distribute its Felix sperm separator in the Czech Republic, Slovakia and Kazakhstan.

Memphasys said that the three-year exclusive Felix agreement had a contracted minimum purchase of \$139,000 in the first year rising to \$310,000 in the third; with about 89,600 assisted reproductive therapy cycles across the three countries.

The company said Invido had exclusivity in the three countries for Felix cartridges and consoles, subject to agreed minimum purchases and other commercial requirements.

Memphasys said the Brno, Czech Republic-based Invido was a specialist supplier of in-vitro fertilization (IVF) and laboratory equipment and consumables; and would lead the commercial development of Felix in the three countries, supported by its “newly established European commercial team”, with the appointment of Arne Schierau as commercial operations head in Europe.

Memphasys director Marjan Mikel said: “We are doing exactly what we set out to do, expanding our footprint, getting Felix into more IVF clinics and building a growing base of recurring cartridge revenue”.

Memphasys was up 0.05 cents or 9.1 percent to 0.6 cents with 2.6 million shares traded.

CURVEBEAM A.I.

Curvebeam says it has raised \$1.75 million in its shortfall offer, taking the total raised with the \$5 million placement and \$610,000 share plan to \$7.36 million.

Curvebeam said that it raised \$606,151 in the share plan at 1.8 cents a share and a further \$1.75 million was placed to Spark Plus Pte Ltd as its corporate adviser, with \$1.39 million through the shortfall offer and \$360,000 in a placement at 1.8 cents a share.

Curvebeam fell half a cent or 15.6 percent to 2.7 cents with 3.3 million shares traded.

ADALTA

Adalta says that a \$US120 million (\$A168.3 million) contract with partner Oribiotech validates its decision to work with cell and gene therapy manufacturer.

In a media release, Oribiotech said it had signed a contract with “an undisclosed bio-pharmaceutical company “to integrate [its] IRO platform into a commercial cell therapy manufacturing process”.

Adalta chief executive officer Dr Tim Oldham told Biotech Daily that the contract “validates our automated technology manufacturing decision.

The company said that the IRO manufacturing platform was the same one it aimed to use for its own cellular immune-therapies.

In a media release to the ASX, Dr Oldham said: “When we chose to deploy IRO we were backing a view that automation is what separates a cell therapy that merely works from a cell therapy that can be sold.”

“A commercial manufacturer has now looked at the same platform and decided to move an already-approved product onto it,” Dr Oldham said.

“Nobody takes that decision lightly - it is the highest bar in our industry,” Dr Oldham said.

“It means the cellular immune-therapies we develop on IRO will be made on a platform that our eventual partners have already validated, endorsed and put into commercial use,” Dr Oldham said.

“That takes a significant question off the table in any future partnering conversation,” Dr Oldham said.

Adalta was unchanged at 0.3 cents with 26.05 million shares traded.

TISSUE REPAIR

Tissue Repair says that 33,338,931 votes (95.20% of its extraordinary general meeting voted in favor of removal from the ASX Official List.

Tissue Repair said that 33,473,844 votes (95.89%) supported the proposed share buy-back.

Last month, the company said that an extraordinary general meeting would vote to approve its removal from the ASX official list and an up-to \$1.0 million share buy-back at 13 cents a share (BD: Aug 17, 2026).

In July, the company said the reasons for delisting included limited liquidity and utility of listing, concentrated shareholder structure, a significant number of small shareholders, cost and administrative burden, as well as strategic flexibility (BD: Jul 23, 2026).

Tissue Repair up 0.1 cents or 1.2 percent to 8.2 cents.

AUSTCO HEALTHCARE

Austco says its annual general meeting will vote to issue chief executive officer Clayton Astles 1,105,992 performance rights, pending financial targets.

Austco said that shareholders would vote to approve the remuneration report and the 10 percent placement capacity, and re-elect director Anthony Glenning.

The meeting will be held in virtually, on October 19, 2026 at 11am (AEDT).

Austco fell two cents or 7.4 percent to 25 cents with 3.3 million shares traded.

COCHLEAR

Cochlear says it has appointed Prof Ian Meredith as an independent non-executive director, effective from December 1, 2026.

Cochlear said that Prof Meredith had more than 30 years' experience merging patient care, clinical research and the development and commercialization of transformative healthcare solutions.

The company said that, most recently, he was Boston Scientific's chief medical officer until 2023, where he led clinical innovation and medical affairs, overseeing 15,000 healthcare products, medical devices and technologies.

Cochlear said that Prof Meredith was currently a director of Transverse Medical and Alleviant Medical.

According to his LinkedIn page, Prof Meredith is a professor of Medicine at Monash University, and holds a Bachelor of Science, as well as a Bachelor of Medicine and Bachelor of Surgery and a Doctor of Philosophy – all from Monash University.

Cochlear fell \$2.49 or 1.8 percent to \$133.90 with one million shares traded.