



# Biotech Daily

Friday June 27, 2025

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market fell 0.43 percent on Friday June 27, 2025, with the ASX200 down 36.6 points to 8,514.2 points.

Twenty-two of the Biotech Daily Top 40 companies were up, 10 fell, six traded unchanged and two were untraded.

Imugene was the best, up 0.2 cents or 18.2 percent to 1.3 cents, with 78.1 million shares traded.

Impedimed improved 13.8 percent; Amplia was up 12.8 percent; Avita climbed 11.1 percent; Actinogen was up 10 percent; Cynata and Nova Eye were up more than nine percent; Neuren was up 6.7 percent; Clarity, Curvebeam and Resonance climbed more than five percent; Orthocell was up 3.3 percent; Cyclopharm, EBR, Medadvisor, Polynovo and Prescient rose more than two percent; with Aroa, Clinuvel, Genetic Signatures, Mesoblast, Nanosonics and Pro Medicus up by one percent or more.

Atomo led the falls (see below), down 0.1 cents or 6.25 percent to 1.5 cents, with 2.8 million shares traded. 4D Medical, Alcidion, Dimerix and Paradigm fell four percent or more; CSL, Immutep, Micro-X and Resmed shed two percent or more; Proteomics, Starpharma and Telix lost more than one percent; with Cochlear down by 0.6 percent.

## DR BOREHAM'S CRUCIBLE: AUDEARA

**By TIM BOREHAM**

**ASX code:** AUA

**Share price:** 2.3 cents

**Shares on issue:** 179,934,383

**Market cap:** \$4.14 million

**Chief executive officer:** Dr James Fielding (co-founder)

**Board:** David Trimboli (chair), Dr Fielding, Hsin-Chieh (Bill) Peng

**Financials\*:** (March quarter 2025): receipts \$1.64 million (up 46%), revenue \$1.26 million (up 230%), cash outflows \$77,000 (previous deficit of \$578,000, cash of \$1.9 million (up 11%) - all comparisons are with the three months to December 31, 2024

**Identifiable major holders:** Fortune Pioneer (David Lin) 19.5%, David Trimboli 13.8%, James Fielding 6.5% Bill Peng 6.25%, Founders 5.08%.

In the days of yore, we either urged grandma to buy a set of hearing aids or YELL AT HER LIKE THIS!!

Of course, many hearing-impaired folk own hearing aids but are loath to wear them, so you still have to YELL AT THEM LIKE THIS!!

But the advent of headphones and buds mean that more augmented hearing tools are available - and the acceptance of having appendages in one's ear means they are more likely to wear them.

The ASX-listed Audeara has developed headphones that adjust the volume and other levels to the wearer's individual profile, with the help of algorithmic-based technology. These aural aids don't replace hearing aids but enhance the ability of hard-of-hearing people to enjoy music, television or Zoom calls and the like.

Audeara co-founder Dr James Fielding says the principle of the platform is "better, not louder". He compares the experience to a driver listening to the radio with the window open and then closing it.

"You haven't changed the volume of your radio by one iota, but your experience is transformed because you have changed other factors."

Over the last two years, Audeara has tweaked its business model from selling its headphones in its own right, to an 'Intel inside' model of providing the technology to big-ticket international customers (see below).

## **Home-grown innovation**

A Brisbane medical graduate, Dr Fielding became frustrated by the ponderous hearing test process while doing his training.

Unlike most folk with good intentions, he did something about it. He devised the technology with fellow Queensland University medical students Chris Jeffery and Alex Afflick (now the company's chief technology officer).

In reality, headphones are merely headphones in a hardware sense. Audeara's "secret sauce" is the in-built testing function that does away with bulky \$15,000 audiometers.

In the testing process, the user dons the headphones and, via beeps, the volume is turned down to the hearing threshold (bear in mind these settings vary not only from person to person, but from left ear to right ear).

Their hearing vision – yes, you read that right – led to them to developing a prototype in 2015 and then a commercial version.

Audeara listed on the ASX in May 2021, having raised \$6 million at 20 cents apiece.

## **Deals, deals, deals**

Audeara's A-01 and A-02 headphones are sold via hearing clinics, notably the Milan-based giant Amplifon which has more than 300 clinics here (and 5,700 centres in 29 countries). The company also won a tender to be the only 'over ear' headphone sold in Amplifon clinics, the world's biggest audiology retailer.

Audeara also sells via Audika Australia, part of the Danish Demant Group.

Audeara accounts for half of all non-hearing aid devices sold under the Federal Government's Hearing Services Program and one-fifth of those provided under the Australian Department of Veterans Affairs banner.

Then there's a deal with Clinico, Taiwan's biggest audiology and hearing aid provider, that involves Audeara providing white-labelled sound buds. The tie-up offers entrée into China.

Clinico launched these devices, Clinico Sound Earbuds CS, on January 22 this year,

Audeara has a presence in 1,500 local audiology (and eyecare) clinics.

The company has tie-ups with Specsavers and a reseller agreement with independent chain George & Matilda Eyecare, which has 115 locations.

The company sold headphones in the US but made the call to exit that market because of an inadequate return on investment.

“It’s all or nothing cracking into the US,” Dr Fielding says. “We weren’t seeing what we needed to keep committing resources to the market.”

He said the company spent a modest \$1 million, “which was not money wasted as it resulted in us gaining Avedis Zildjian as a partner.”

## **A cymbal of success**

Avedis who?

The world’s oldest musical instrument maker, that’s who.

In February 2024, Audeara won its first purchase order from the company, which makes cymbals, drumsticks, gongs and other percussive paraphernalia.

Audeara supplies the personalized sound algorithms for Avedis Zildjian’s Alchem-E Perfect Tune headphones.

Founded in Constantinople (now Istanbul) by Armenian Avedis Zildjian, the company is one of the world’s longest continuous-operating enterprises with a 400-year history.

(A family name conferred by the prevailing Sultan Mustafa I, Zildjian literally means ‘cymbal maker’ in Turkish).

Avedis Zildjian now operates from Norwell, Massachusetts but remains controlled by the Zildjian family.

These days, all Zildjian instruments are made in the US at the company’s cymbal factory in Norwell and drumstick/mallet facility at Newport, Maine.

## **Am I hearing that price correctly?**

Why are hearing aids so damned expensive?

Dr Fielding notes the physical cost of building a hearing device - in effect a blob of plastic with electronic componentry - is around \$20.

Yet, consumers end up paying \$10,000, or \$15,000 or more.

As with a new drug which might cost a few cents to make but could sell for thousands of dollars, the cost of a hearing aid covers the research and development, the clinicians’ time and the retailers’ and distributors’ margins.

“From a business point of view they are solving a very big problem,” he says, in reference to the knock-on effects of hearing loss such as social isolation, depression and dementia.

He adds: “The difference between a good and bad one is distinctly notable: they are chalk and cheese.”

There’s also an element of charging what they can charge because the industry is an oligopoly, with five groups accounting for 90 percent of the market.

But with US regulatory changes that enhance the availability of much cheaper over-the-counter (OTC) hearing aids, the times they are a-changing.

“The changes mean a device priced at more like an Airpod than a hearing aid could do the job for a large number of people who aren’t ready to make the next step.”

### **Coming to the (aid) of needy patients**

In September last year, Audeara signed a letter of intent with Taiwan’s Eastech to bring hearing aids to the Chinese market.

There are key distinctions between the Eastech and Clinico deals.

As opposed to ear buds, the Eastech tie-up pertains to medical devices – hearing aids - that are formally designated as such.

Rather than a co-branding arrangement as per Clinico, Audeara provides the background technology to Eastech and ‘clips the ticket’ on each unit sold.

The hearing aids are marketed under a separate, well known hearing aid brand.

The devices will be licenced for distribution in China under Eastech’s National Medical Products Administration (NMPA) certification.

Given they are sold via hearing clinics, the Audeara headphones have more gravitas than headphones sold at, say JB Hi-Fi.

Dr Fielding notes Audeara is not a medical device manufacturer, but a technology provider.

Audeara itself does not have to go through the rigmarole of ongoing compliance and certification.

“For a company that wants to launch a hearing aid product, we can provide the tech and the know-how,” he says.

“We are not trying to beat the \$12,000, top-tier hearing aids,” he says.

“But we offer an incredible solution to enhance hearing, as well as our secret sauce on the entertainment front.”

## **Financials and performance**

On June 18, Audeara said revenue for the 11 months to May 31, 2025, was a record \$3.64 million, up 14 percent year on year.

The growth was driven by Clinico's ear bud launch and co-branded partnerships, while Australian wholesale revenue grew 17 percent to \$1.67 million.

In April, Audeara reported March (third) quarter revenue of \$1.26 million, 230 percent higher than the December 2024 quarter and 113 percent better year-on-year.

Cash outflows were \$73,000, an improvement on December quarter's \$578,000.

The company had \$1.9 million in cash at March 31, 2025.

During the quarter, Clinico lodged an initial order of \$570,000.

The company also received a second \$1.5 million purchase order from Avedis Zildjian, following an initial \$2.1 million order in early 2024.

About 50 percent of Audeara's revenue derives from Australia, but overseas revenue is likely to account for two-thirds by the end of 2025.

Over the last 12 months, Audeara shares have whispered between 6.0 cents (late September last year) and the current trough of 2.1 cents.

The shares peaked at 16 cents just after listing.

The company's biggest shareholder is Clinico's David Lin, who took a 20 percent Audeara stake as part of the deal.

## **Local reimbursement remains strong despite NDIS dip**

While the headphones are not devices, Audeara enjoys the best of both worlds in that they are still reimbursable by government insurers.

Locally, the tab is picked up by the Federal Hearing Services Program (HSP) and the Department of Veterans Affairs (DVA) rehabilitation program.

Then there's the National Disability Insurance Scheme - NDIS - an entrée to one million eligible users. Last year, the NDIS accounted for 10 percent of local revenue.

The NDIS funding falls into the categories of 'daily adaptive devices' and 'hearing specific'. With the latter, a whopping 25 to 30 percent of people on the NDIS are eligible.

But NDIS revenues have "softened" from September as a result of the agency's restructure, as changes meant recipients had less discretion after receiving funding.

“Our biggest markets always have been the DVA and the HSP,” Dr Fielding says.

“The NDIS was a great contributor to the bottom line, but we haven’t put a tremendous focus on it.”

The NDIS revenue contribution is now more likely to be in the low single digits.

### **Dr Boreham’s diagnosis:**

“I know of judges who don’t wear hearing aids,” Dr Fielding says. “When is it more important to be hearing what someone is saying?”

Indeed - justice should be blindfolded (impartial), but not deaf.

It’s disturbing to hear - or not hear - the extent of undiagnosed hearing loss.

Depending on who you ask, about 10 percent of the world’s 10-year-olds and up to 50 percent of 75-year-olds are hearing impaired.

The World Health Organization estimates that one billion people aged under 30 will have a life-affecting hearing loss by 2030.

Cochlear aside, Audeara is the only ASX-listed audiology pure play. Another exponent, Nuheara, called in the voluntary administrators in August last year.

This was despite Nuheara’s “successful” launch of its over-the-counter hearing aids in the US - and because of a breakdown in negotiations with a convertible noteholder.

However, Nuheara’s Iqbuds are still available via retailers.

Dr Fielding says he was inspired to start Audeara because of Nuheara’s “clever” tech.

Audeara shares have disappointed since listing, although the company’s wholesale approach may avoid the pitfalls of relying on large ‘big box’ retailers.

Dr Fielding has been topping up his shareholding “and I wouldn’t do that if I didn’t think there was extraordinary upside at the other end”.

While the high-margin legacy headphone business accounts for most of Audeara’s earnings, Dr Fielding tips the third-party revenue eventually will dwarf the existing business.

“If we get three or four Zildjian-esque accounts it provides a sure-fire path to cash-flow break even and profitability and then we are properly rocking and rolling”.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. What??!!There’s no need to shout!!***

## ATMO BIOSCIENCES

Atmo says it has US Food and Drug Administration 510(k) clearance to market and sell its ingestible, gas-sensing capsule for diagnosing gut motility disorders.

The Melbourne-based Atmo said the FDA decision was based on a pivotal clinical study in which 209 subjects at 11 US sites and one Australian site ingested either the Atmo gas capsule or a predicate device called Smartpill.

Last year, the company said the study for suspected gastro-intestinal motility disorders met its primary endpoint; and later, said the study validated its capsule for assessing gastro-intestinal transit times to assist with diagnosis (BD: Apr 9, 2024; Mar 5, 2025).

In April, Atmo said the Royal Melbourne Institute of Technology had transferred all patents and associated intellectual property related to its gas capsule “in exchange for an equity stake in the company” (BD: Apr 15, 2025).

At that time, Atmo chief executive officer Mal Hebblewhite told Biotech Daily that Atmo had re-filed a 510(k) application to the FDA about two weeks prior and was seeking Conformité Européenne mark certification for its gas sensing capsule in Europe.

Today, the company said the capsule would be available in the US from July 2025.

Atmo said its gas capsule assessed “both whole and regional gut transit times, covering the stomach, small bowel, and colon, to aid in diagnosing gastrointestinal motility disorders”, including gastroparesis, or the delayed emptying from the stomach, and slow transit constipation, both of which were treatable conditions.

The company said by measuring regional and whole gut transit the capsule eliminated “the need for more cumbersome procedures such as gastric scintigraphy or radio-opaque marker studies and avoids exposing patients to radiation”.

Mr Hebblewhite said the company was “thrilled” to have FDA clearance.

“The Atmo gas capsule is a much-needed test that gives clinicians comprehensive, clinically valuable information so they can diagnose and manage patients quickly, conveniently, and accurately,” Mr Hebblewhite said.

Atmo is a public-unlisted company.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has completed its acquisition of Perth’s Isopogen WA and its Stems smart technology for scrip and has replaced its chair and a director.

Last month, Neuroscientific said it would acquire Isopogen WA and its Stems smart cells for indications including Crohn’s disease (BD: Apr 16, 2025).

Today, the company said it had begun a special access program of the Stems smart mesenchymal stem cells for fistulizing Crohn’s disease.

Neuroscientific said it had appointed Isopogen directors Robert McKenzie and Paul Fry as non-executive chair and non-executive director, respectively, with chair Christopher Ntoumenopoulos and director Tony Keating resigning, effective from today.

The company said Mr McKenzie and Mr Fry would receive 5,000,000 options, each, exercisable at seven cents each within three years from the issue date.

Neuroscientific said it intended to enter “into a consultancy arrangement with Mr Fry in respect to the provision of management services, charged at a day rate, to be conducted during a transitional period” and it had appointed Isopogen director Dr Marian Sturm as chief scientific officer.

Mr McKenzie said the company’s “immediate focus will be on a special access clinical program in fistulizing Crohn’s disease which is challenging to treat and where sustained healing has proven limited with standard therapies”.

Neuroscientific was up 0.6 cents or 8.1 percent to eight cents.



### ATOMO DIAGNOSTICS

Atomo says it has raised \$272,387.50 at 1.85 cents a share in a share purchase plan, leaving a \$727,612.50 shortfall and taking the total raised to \$2,385,388.

Last month, Atomo said it had "commitments" to raise about \$2,113,000 in a placement at 1.85 cents a share, a six percent discount to the 15-day volume weighted average price, with a \$1.0 million, non-underwritten share plan to follow (BD: Apr 24, 2025).

Today, the company said investors would receive one option for every share issued, exercisable at four cents each by June 27, 2028.

Atomo said it "reserved the right to place the share purchase plan shortfall".

Atomo fell 0.1 cents or 6.25 percent to 1.5 cents with 2.8 million shares traded.

### ORTHOCELL

Orthocell says the first US commercial surgery using its Remplir collagen wrap for nerve repair has been completed at an unnamed Ohio hospital.

Earlier this year, Orthocell said it had US Food and Drug Administration 510(k) clearance to begin commercial distribution of Remplir in the US (BD: Apr 4, 2025).

Today, the company said the surgery used Remplir manufactured at its Perth, Western Australia facility in a procedure to repair a foot nerve injury and was observed by its medical education team.

Orthocell managing-director Paul Anderson said the first US surgery was "a significant milestone for Orthocell and for the roll-out of Remplir in the US".

"It signals the start of our commercial journey in the world's largest healthcare and nerve repair markets, and reflects our commitment to delivering innovative, clinically proven solutions to surgeons and their patients," Mr Anderson said.

"A critical first step in the US starts with getting Remplir into surgeons' hands for them to gain familiarity with its key features and benefits in clinical practice," Mr Anderson said.

"These early cases play an important broader strategic role in building experience and knowledge amongst the surgical community," Mr Anderson said.

"We are confident our efforts in the US are on track to drive material growth in sales of Remplir during the second half of calendar 2025," Mr Anderson said.

Orthocell was up four cents or 3.3 percent to \$1.25 with 1.3 million shares traded.

### IMUGENE

Imugene says it has dosed the first patient in its Australia and UK, investigator-sponsored, phase II trial of PD1-Vaxx for operable colorectal cancer.

In 2023, Imugene said it would conduct an up-to 44-patient, phase II trial of its PD1-Vaxx vaccine for colorectal cancer in Australia the UK with the University of Southampton, the Royal Surrey Hospital National Health Service Foundation Trust and the Australasian Gastro-intestinal Trials Group (BD: Dec 6, 2023).

At that time, the company said the primary objective of the study would be to determine pathological response rates by measuring tumor size.

Earlier this month, Imugene said it opened the phase II trial at Adelaide's Queen Elizabeth Hospital, the first Australian site (BD: Jun 2, 2025).

Imugene was up 0.2 cents or 18.2 percent to 1.3 cents with 78.1 million shares traded.

## PYC THERAPEUTICS

PYC says it will present in-vivo data of PYC-002 for Phelan-McDermid syndrome (PMS) at the PMS Global Congress in Barcelona, Spain from June 26 to 29, 2025.

Last year, PYC said pre-clinical studies showed PYC-002 “addresses the underlying cause of Phelan-McDermid syndrome”, in animals (BD: Dec 16, 2024).

At that time, the company said the pre-clinical studies showed PYC-002 increased SHANK3 gene expression in the critical regions of the brain implicated in Phelan-McDermid syndrome, in animal models and that the underlying cause of the disease was “insufficient expression of the Shank3 gene in neurons within the brain”.

Today, the company said it was currently progressing the drug “through the final pharmacokinetic and dose-range finding studies required before initiating formal investigational new drug-enabling studies”.

PYC said it expected PYC-002 “to enter human trials next year”.

PYC was up half a cent or 0.4 percent to \$1.27.