

Biotech Daily

Friday August 15, 2025

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.73 percent on Friday August 15, 2025, with the ASX200 up 64.8 points to 8,938.6 points. Twenty-four of the Biotech Daily Top 40 companies were up, nine fell and seven traded unchanged.

Curvebeam was the best, up one cent or 8.3 percent to 13 cents, with 450,155 shares traded; followed by Starpharma up one cent or eight percent to 13.5 cents, with 363,528 shares traded. 4D Medical climbed 7.55 percent; Paradigm was up 6.35 percent; Amplia, Impedimed and Orthocell were up five percent or more; Actinogen was up four percent; Botanix, EBR, Immutep and Mesoblast were up three percent or more; Emvision, Micro-X, Resonance, SDI and Telix rose more than two percent; Avita, Clarity, Cochlear, Cyclopharm, Genetic Signatures, Imugene and Nanosonics were up one percent or more; with Clinuvel, CSL and Resmed up by less than one percent.

Universal Biosensors led the falls, down 0.3 cents or 13.6 percent to 1.9 cents, with 3.2 million shares traded. Nova Eye lost 6.45 percent; Medical Developments was down 5.6 percent; Cynata fell 4.9 percent; Syntara was down 3.6 percent; Optiscan shed 2.4 percent; Medadvisor and Neuren were down more than one percent; with Aroa and Pro Medicus down by less than one percent.

DR BOREHAM'S CRUCIBLE: RADIOPHARM THERANOSTICS

By TIM BOREHAM

ASX code: RAD

Nasdaq code: RADX

Share price: 2.6 cents; Shares on issue: 2,364,949,502; Market cap: \$61.5 million

Chief executive officer: Riccardo Canevari

Board: Paul Hopper (executive chair), Mr Canevari, Ian Turner, Hester Larkin, Dr Leila Alland, Phillip Hains, Noel Donnelly

Financials (June 2025 quarter): revenue nil, receipts \$829,000 (\$5.36 million for the year) from its Lantheus relationship, net operating cash outflows \$7.03 million (\$36.6 million for the year), cash balance \$29.1 million.

Identifiable major holders: Lantheus 12.1%, Paul Hopper 6.3 %, Regal Funds 6.2%, OC Funds 4.1%, Nanomab Tech 2.7%

Radiopharm Theranostics pales in size relative to ASX peer Telix Pharmaceuticals and US nuclear medicine titan Lantheus, but CEO Riccardo Canevari is happy to walk in the shadow of giants.

Mr Canevari notes the duo's pioneering role in creating a \$US1.5 billion-a-year-market for their prostate cancer imaging agents, Illuccix and Pylarify, respectively.

Previous to that, the biggest radiotherapy was the \$US100 million a year Netspot, developed by Mr Canevari's former employer Novartis for neuro-endocrine tumors.

But the prostate cancer market now is crowded, with up to 40 agents targeting the common biomarker prostate specific membrane antigen (PSMA).

While Radiopharm has a prostate cancer agent in development, it's targeting the prostate specific antigen (PSA) and it's by no means the company's sole focus.

All up, the company has five programs at clinical stage in multiple indications and it should start a sixth by the end of the year.

The prostate cancer giants set the benchmark.

"What Telix and Lantheus have done has been transformational for the sector in that they have grown the market by 15 times," Mr Canevari says.

"I would be very happy to copy what they did, but just with a different product."

About Radiopharm

Radiopharm is about pairing diagnostic scans with companion radionuclide therapies, emphasizing precision, safety and novel oncology targets.

With a \$59 million market valuation, Radiopharm might be a minnow, but its agenda spans multiple programs including peptides, small molecules and monoclonal antibodies.

"If nuclear medicine works well in prostate cancer, why shouldn't it work well in other solid tumors," Mr Canevari says.

A creation of biotech entrepreneur Paul Hopper, Radiopharm listed on the ASX on November 25, 2021, raising \$50 million at 60 cents apiece. The company listed on the Nasdaq in late November 2024.

In late December 2024, Radiopharm and the aforementioned, Nasdaq-listed Lantheus unveiled a "co-development" agreement, by which Lantheus would stump up for a phase I imaging trial in an area of unmet need.

Radiopharm is based on assets acquired from Imperial College London, New York's Sloan Kettering Memorial Hospital and the Technical University of Munich.

The New York City-dwelling Mr Canevari joined in September 2021, having spent 11 years at Novartis (including as head of the breast cancer franchise).

What's in a name?

The 'theranostics' in the company's name refers to developing both diagnostic and therapeutic radiopharmaceuticals for cancer.

The diagnostic leg involves the use of lower energy radioisotopes to allow physicians to 'see' and measure tumors. The treatment bit involves higher-energy particles. The process involves attaching a radioactive isotope to a targeting agent, such as a small molecule or antibody.

"With the same molecule using different isotopes you can have an imaging agent to detect where the tumor is – both large tumors and small metastases," Mr Canevari says. "Then you switch isotopes to get the therapeutic model going to the same place the imaging agent went."

RAD-101 takes flight

Radiopharm's most advanced program, RAD-101, aims to develop an imaging tool for brain metastases. It involves using the isotope F18 (not the fighter jet) and combining it with a radio-tracer called pivalate, for use in positive emission tomography (PET) imaging.

In the US, an open-label, single-arm, phase IIb, clinical trial is underway, enrolling 30 patients with confirmed recurrent brain metastases.

An earlier phase II trial showed the injected radio-tracers migrated to the tumors effectively.

Here's a fun fact: the US brain metastases (mets) market is bigger than that for prostate cancer, with 300,000 new patients a year compared with 270,000 to 280,000 for the latter.

"It's a very large patient population and addressable market," Mr Canevari says.

"All we need is good scientific data and good execution and keep going."

The indication should not be confused with gliomas - primary brain tumors - which Telix is pursuing with a proposed agent the FDA has refused to approve (for the time being).

Radiopharm expects to announce interim data by the end of 2025.

Why hasn't anyone else seized the opportunity?

"We are the only company with a phase II imaging trail for brain metastases," Mr Canevari says.

Ok. But why?

"The answer is because it is difficult," Mr Canevari says. "To image the brain, you need a molecule that is very small and able to cross the blood-brain barrier and have a selective uptake in the brain mass."

He notes an Italian developer, Bracco Imaging abandoned a phase III imaging program.

"We thought six months ago we had a competitor ahead of us, but now officially they have dropped [off]," he says.

Mr Canevari says some agents have been glucose based, which is a problem because the brain contains a lot of sugar and thus the imaging contrast isn't great.

RAD101 targets the fatty acid synthase, which is over-expressed in cancerous brain cells but not healthy ones.

Mr Canevari says standard-of-care magnetic resonance imaging (MRI) scans work quite well for assessing brain 'mets' initially. But after treatment - typically with stereotactic radio-surgery (radiation beams) - there's more dead brain tissue that makes imaging harder.

RAD204's multi-tumor approach

RAD204 is subject to a first-in-human phase I therapy trial for advanced solid tumors expressing the PD-L1 antibody.

The nanobody is radio-labeled with Lutetium 177 (177-Lu-RAD204 to friends).

Following data and safety monitoring committee approval in May, the trial can dose a second cohort at one and a half times stronger than the initial delivery.

The trial enrolls patients with multiple tumor types, including non-small cell and small cell lung cancer, triple-negative breast cancer, cutaneous melanoma, head and neck squamous cell carcinoma and endometrial cancer.

Investors should see results from the first two cohorts by the end of 2025.

RAD202: the Heat is on

Also powered by lutetium, 177Lu-RAD202 targets HER-2 positive solid tumors. (HER-2 stands for human epidermal growth factor receptor-2).

Mr Canevari says RAD202 is the only HER-2 breast radio-pharmaceutical therapy in clinical stage.

"We have the potential to be first to market with this product, assuming the science is nice to us."

In June 2025, Radiopharm dosed the first patient in its phase I, open-label dose escalation trial, dubbed Heat.

The trial should determine the recommended dose for a phase II study and "evaluate the safety and preliminary clinical activity" for a variety of HER-2 cancers.

Covering 10 HER2-positive breast cancer patients, a previous phase I study showed "clinical proof-of-concept as well as the safety and distribution of RAD202".

Once again, investors can expect clinical data from the first two cohorts by the time Santa arrives this year.

Crank up the RV and hit the road

In a joint venture, Radiopharm and the Houston, Texas MD Anderson Cancer Centre are running a program called RV-01 (Betabart).

In July 2025, the FDA granted assent for a first-in-human, phase I, therapeutic trial in solid tumors. This is expected to kick off by the end of 2025.

RV refers not to recreational vehicles, but the joint venture vehicle Radiopharm Ventures.

A monoclonal antibody, RV-01 targets the B7-H3 antigen, a novel mechanism of action. B7-H3 is highly expressed in tumors and "associated with poor prognosis in many cancer types".

The company says RV-01 enables enough time for the agent to target the tumors, while the liver deals with monoclonal antibodies better than peptides or small molecules.

There's more ...

Radiopharm plans to submit for ethics approval to begin a phase I trial in prostate cancer, using 161Tb-RAD402.

161Tb-RAD402 what?

Okay - it's an "anti-kallikrein related peptidase 3 monoclonal antibody radiotherapeutic labelled with Terbium 161".

Crucially, the trial targets the prostate-specific antigen (PSA) rather than the prostate-specific membrane antigen (PSMA).

The difference is more than a case of the Judean Peoples' Front versus the Peoples' Front of Judea.

Found in the blood, PSA indicates potential prostate cancer. Found on the surface of cancerous cells, PSMA is more useful for imaging confirmed prostate cancer cases.

Mr Canevari says some patients don't respond to a PSMA-targeting agent and "could benefit from an additional line of therapy".

He doesn't believe the company would compete with Novartis' market-leading prostate cancer therapy, Pluvicto.

Also, Radiopharm has FDA approval for a pancreatic imaging trial, RAD301.

RAD301 road tests a gallium radio-labelled asset called Ga-68-RAD301, targeting the avBeta integrin antibody.

Integrins are cell surface receptors that play crucial roles in cell signaling, migration and survival.

An open-label, phase la study is evaluating "biodistribution" in subjects that include healthy volunteers and pancreatic cancer patients.

Finances and performance

A year ago, Radiopharm raised \$70 million, consisting mainly of a \$62.5 million institutional placement struck at four cents a share (an 18 percent premium).

In an "initial strategic investment", Lantheus chipped in \$7.5 million at five cents a share (an almost 50 percent premium).

In January this year, Lantheus doubled down with a further \$8 million placement, at six cents a share.

Lantheus is now Radiopharm's biggest holder with a stake of just under 7.0 percent. So, the Lantheus 'giant' is part of the Radiopharm 'shadow'.

Last month, Radiopharm reported June quarter receipts of \$829,000, taking receipts for the year to \$5.36 million, related to the Lantheus deal.

June quarter cash burn came in at \$7 million for the quarter and \$36.6 million for the year.

Radiopharm has cash of \$29.1 million, enough to last until mid-2026.

"We are in a good position," Mr Canevari says.

"But we will remain opportunistic [about a further raising] and see if there is a right time to go to market."

While Clarity raised its \$200 million locally, Radiopharm's Nasdaq listing enhances the prospect of tapping US investors.

Over the last 12 months Radiopharm shares have ranged between 4.2 cents (mid-January this year) and two cents (late July 2025).

Dr Boreham's diagnosis:

"Our molecules are well differentiated in areas where no other radio-pharmaceutical company is currently developing products," Mr Canevari says.

In soccer terms, Radiopharm has multiple shots at goal, but Mr Canevari acknowledges that not every 'ball' will hit the back of the net.

While Clarity recently ditched some second-string programs from its packed agenda, Mr Canevari reckons half a dozen programs - equally split between imaging and therapy - are about right.

"It's hard to think that all six will work perfectly - that's part of the risk - but there's a good probability that one or two will be the bright spot."

Mr Canevari says the company might only be a couple of years off commercializing the brain imaging RAD-101, which has FDA fast track designation.

He cites an US addressable market of \$US500-600 million a year, "but it takes time to build".

Unlike Telix and Clarity holders, Radiopharm investors are yet to be rewarded for their patience. The shares have never recovered from listing day, when they tumbled by one third.

But would Lantheus waste time with an isotopic no-hoper that's a small shadow of itself?

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has walked in the shadow of many journalistic greats – and some of them occasionally were sober.

COCHLEAR

Cochlear says record revenue for the year to June 30, 2025 was up 4.8 percent to \$2,343,100,000, with record net profit after tax up 9.0 percent to \$388,900,000.

Cochlear said revenue from sales of its cochlear implants increased 10.6 percent to \$1,470.2 million, services including sound processor upgrades fell 9.4 percent to \$609.2 million and acoustics product sales rose 7.8 percent to \$276.4 million.

The company said cochlear implant sales increased due to "a 12 percent increase in implant units to 53,968" for the year to June 30, 2025, with units sold in emerging markets up 20 percent and developed countries up six percent "slightly below expectations due to slower market growth".

At its 2025 result analyst and media briefing, Cochlear chief executive officer Dig Howitt said sales were below expectations for the year to June 30, 2025.

Last year, Mr Howitt said the company was targeting a net profit guidance for the year to June 30, 2025 of \$410 million to \$430 million, which was a six percent to 11 percent increase (BD: Aug 15, 2024).

In February, the company said it expected net profit to be at the lower end of guidance due to a lower contribution from services revenue and higher cloud-related investment. Today, Mr Howitt said cost-of-living pressures, particularly in the US, had delayed the uptake of hearing implant upgrades, it had implemented payment plan options and expected increased upgrades in the year to June 30, 2026.

Cochlear said Americas revenue fell 0.3 percent to \$1,137.3 million, revenue from Europe, the Middle East and Africa rose 5.9 percent to \$789.7 million, with sales in the Asia-Pacific up 15.3 percent to \$428.8 million, compared to the prior corresponding period.

"Growth in the eligible base slowed due to lower growth five years ago and Covid-19 delays to the last sound processor replacement cycle," Mr Howitt said. "Our investment in [research and development] ... has increased year on year, when sales have gone down, our [research and development] has continued to lift."

Mr Howitt said research and development was "the core of our business".

Cochlear said research and development expenditure was \$291.5 million, or 12.4 percent of revenue, up 5.2 percent on the previous corresponding period.

Mr Howitt said in the year to June 30, 2026 it expected "underlying net profit of \$435 million to \$460 million, an 11 percent to 17 percent increase on 2024-'25".

"We expect strong revenue growth in developed markets from the launch of the new Nucleus Nexa implant, moderated by lower growth in emerging markets revenue, with overall revenue and earnings growth weighted to the second half," Mr Howitt said.

In June, Cochlear said it would launch Nucleus Nexa as the "world's first and only smart cochlear implant system" in Europe and Asia Pacific (BD: Jun 12, 2025).

Last month, the company said it had US Food and Drug Administration approval for its Nucleus Nexa System and Nucleus Kanso and Kanso 3 Nexa sound processors, with US commercialization expected by October 2025 (BD: Jul 8, 2025).

The company said it would pay a partly-franked dividend of \$2.15 a share for shareholders at the record date of September 19 on October 13, 2025, up 2.4 percent on the \$2.10 per share partly-franked dividend paid in the prior corresponding period.

Cochlear said diluted earnings per share rose 9.2 percent to \$5.928, with net tangible assets per share up 4.5 percent to \$22.165 compared to \$21.216 in the prior year.

The company said it had cash and cash equivalents of \$275.7 million at June 30, 2025 compared to \$513.6 million at June 30, 2024.

Separately, Cochlear said it had extended its on-market buy-back, intending to buy up-to \$75 million worth of its shares from August 29, 2024 to August 28, 2026.

Cochlear was up \$3.04 or one percent to \$309.03 with 346,834 shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has \$3 million from the Federal Government to conduct studies of its portable 'Emu' brain scanner for improving stroke care in regional Australia.

Emvision said the grant was awarded by the Federal Government's Cooperative Research Centres Projects (CRC-P) program and would be used to show the clinical benefit of its device, "a central requirement for hospital and health network purchase decision-making". The company said the study at South Australian regional hospitals would use its scanners with telehealth and dedicated stroke nurses to show they provide timely diagnosis. Emvision said the trial would be "the first study to demonstrate the benefit of the Emu point-of-care brain scanner in clinical use" and would provide a "stroke care workflow for regional Australia", with the study data to be used for commercialization of Emu, subject to Australian Therapeutic Goods Administration clearance.

Emvision said it would partner with Titan Pre-hospital Innovation, the Australian Stroke Alliance and South Australian Rural Support Service for the study.

Emvision was up 4.5 cents or 2.6 percent to \$1.75.

ANTEOTECH

Anteotech says it will not proceed with the \$1.4 million grant from the Queensland Government for its ultra-high silicon anode battery additive for electrical devices. Last year, Anteotech said the Queensland Government had awarded it a \$1.39 million grant to develop its battery anode (BD: Mar 27, 2024).

Today, the company said accessing the funds required a \$2.2 million investment, including \$1.2 million a year to maintain the minimum headcount threshold. Anteotech said it would instead test cell design performance at "significantly lower costs" to allow resources to be invested into commercializing market-ready products. Anteotech was up 0.1 cents or 4.35 percent to 2.4 cents with 8.4 million shares traded.

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION. HERAMED

The Therapeutic Goods Administration says "there are no home-use foetal heart monitors approved by the TGA for supply in Australia" including Heramed's.

The TGA said adverse outcomes relating to the use of home-use foetal heart monitors continued to be notified to the regulator and that "using a home-use foetal heart monitor to check a baby's heartbeat may seem reassuring but it can be dangerously misleading". On October 28, 2024, the Administration said after a post-market review it removed "all home-use foetal dopplers that were intended to be used without the supervision of a healthcare professional" from the Australian Register of Therapeutic Goods.

The TGA said it had cancelled systems manufactured by Heramed, Shenzen Jumper, Edan Instruments, Bistos Co and Laerdal with devices sponsored by Heramed, Macquarie Medical, Cabrini Health, Laerdal, Le Reve Healthcare, Device Technologies and others. Last year, Heramed said the TGA cancelled all home-use foetal dopplers devices, including its Herabeat foetal heart rate monitor (BD: Sep 27, 2024).

The regulator said its review had "confirmed that the lack of specialized training to use these devices could result in false reassurance of the health of a baby".

The TGA said "where a foetal doppler device is cancelled from the ARTG, they are not being recalled from the market ... [and] the cancellation means home-use devices will no longer be available for purchase".

The Administration said there "may be resale of second-hand devices".

Heramed fell 0.1 cents or 4.2 percent to 2.3 cents with 2.45 million shares traded.

THE UNIVERSITY OF NEW SOUTH WALES

The University of New South Wales (UNSW) says it has developed "a new generation of Crispr technology ... [for] a safer path to treating genetic diseases like sickle cell".

The University of New South Wales said a study found that chemical tags once regarded as genetic clutter were "powerful gene silencers and removing them could unlock safer treatments for inherited blood disorders".

The University said the study, titled 'Removal of promotor CpG methylation by epigenome editing reverses HBG silencing' was published in Nature Communications, with the full article available at: http://bit.ly/3JybqKI.

The University of New South Wales said it used clustered regularly interspaced short palindromic repeats (Crispr) to "deliver enzymes that remove methyl groups from DNA, effectively lifting the brakes on silenced genes".

The University said Crispr "harnesses what is already a naturally occurring process, first observed in bacteria fighting off invading viruses by 'snipping' the virus DNA strands". The University of New South Wales said the first generation Crispr cut DNA sequences to disable faulty genes and the second generation allowed researchers to "zoom-in and correct individual letters in the genetic code" and both risked unwanted changes, while the

third generation, epigenetic editing, removed methyl groups attached to silenced or suppressed genes.

The University said it would use its Crispr technology to switch-on the foetal globin gene that delivered oxygenated blood to a developing foetus in utero, which could "provide a neat workaround for the faulty adult globin gene that has caused sickle cell diseases". The University of New South Wales said the studies in human cells were "not only promising for people with sickle cell disease, but other genetic diseases, where turning certain genes on or off by altering the methyl groups, avoids having to cut DNA strands". The University said its researchers would "test the efficacy of these approaches in animal models but also try more Crispr related tools".

NEURIZON THERAPEUTICS (PHARMAUST)

Neurizon says the US Food and Drug Administration will decide on the clinical hold of its investigational new drug application for NUZ-001 by October 3, 2025.

Last month, Neurizon said the FDA confirmed it would lift a clinical hold on NUZ-001 for amyotrophic lateral sclerosis (ALS) pending two pre-clinical pharmaco-kinetic studies; and later, said it had filed a formal response to the FDA including pharmaco-kinetic data in rats and dogs (BD: Jul 10, 2025).

Today, the company said the FDA's standard review period for clinical hold complete responses was within 30 days and that the delay was "not a reflection on the quality or completeness of Neurizon's submission".

Neurizon said the delay was "the result of broader strain in the FDA's capacity caused by agency-wide restructuring and staffing reductions under recent administrative reforms, impacting the FDA's ability to maintain timely review cycles".

The company said "similar delays have been experienced by other ALS programs ... due to internal FDA workload pressures".

Neurizon managing-director Dr Michael Thurn said the delay was "extremely disappointing" particularly given the straightforward information provided in our response". "The FDA has acknowledged persistent resourcing challenges, which have been exacerbated by organisational changes implemented under the current administration, resulting in increased review backlogs," Dr Thurn said.

Neurizon fell two cents or 11.8 percent to 15 cents with 2.1 million shares traded.

VGI HEALTH TECHNOLOGY LTD

(FORMERLY INVICTUS BIOTECHNOLOGY, AZURE HEALTH TECHNOLOGY)

VGI says it will delist from the National Stock Exchange (NSX), change its name to 'Invictus Therapeutics', list in the US and conduct a five-to-one share consolidation. In 2021, the then Azure said it expected to list on the National Stock Exchange (previously the Newcastle Stock Exchange) on May 28, 2021 under the code 'VTL' and change its name to VGI Health Technology (BD: May 20, 2021).

Today, the company said it was conducting two phase II trials of its transmucosal tocotrienol IVB001 in non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steato hepatitis (NASH) as well as IVB003 in pancreatic adeno-carcinoma.

VGI said it expected data relating to safety, tolerability and efficacy from both phase II trials "in the next three years" and expected to bring a further class of drugs, IVB002 and IVB004, into the clinic "in the next 18-to-24 months".

The company said the additional drugs had been shown "to achieve a much higher bioavailability than transmucosal or orally-delivered tocotrienols in an animal model". VGI said it would delist from the National Stock Exchange, with New York's Maxim Group LLC appointed financial advisor for a US listing.

The company did not disclose what US exchange it would list on, nor whether it would raise capital for the listing.

VGI said it would change its name to 'Invictus Therapeutics Ltd' "to better reflect the company's key focus which is the development of drugs based on improved delivery of tocotrienols".

The company said it would conduct a "five-to-one reverse-split of its shares reducing the total number of shares on issue from 138,246,523 shares to 27,649,305 shares". On the NSX, VGI was in a suspension and last traded at two cents.

ISLAND PHARMACEUTICALS

Race Oncology managing-director Dr Daniel Tillett says he has reduced and been diluted in Island from 14,127,577 shares (6.72%) to 14,010,000 shares (5.55%).

The Sydney-based Dr Tillett said that he sold 127,577 shares on May 22 and 23, 2025 for \$27,619, or 21.65 cents a share, bought 10,000 shares on June 30, 2025 for \$1,310, or 13.1 cents a share and was diluted due to a capital raise and option exercises between May 29 and August 11, 2025.

In May, Island said it had "commitments" to raise \$3.6 million at 15 cents a share, an 11.86 percent discount to the 15-day volume weighted average price, in a placement to institutional, sophisticated and professional investors (BD: May 21, 2025).

Last month, the company said it had raised \$779,944 from the San Juan, Puerto Ricobased substantial shareholder and co-founder Dr Bill Garner through the exercise of 11,142,061 options at seven cents each (BD: Jul 17, 2025).

On Monday, Island said it had raised \$350,000 from Hong Kong's MWP Partners through the exercise of 5,000,000 options at 7.0 cents each (BD: Aug 11, 2025). Island was up one cent or 5.4 percent to 19.5 cents.