Biotech Daily

Friday September 12, 2025

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market improved 0.68 percent on Friday September 12, 2025, with the ASX200 up 59.9 points to 8,864.9 points. Seventeen of the Biotech Daily Top 40 companies were up, 14 fell and nine traded unchanged.

Atomo was the best, up 0.4 cents or 22.2 percent to 2.2 cents, with 17.9 million shares traded. Curvebeam climbed 14.9 percent; Botanix was up 13.6 percent, Dimerix improved 9.6 percent; Amplia was up 6.45 percent; Avita and Resonance rose more than five percent; Alcidion, Clarity and Neuren were up more than three percent; CSL, Emvision, Nova Eye, Optiscan and Paradigm climbed one percent or more; with Cochlear, EBR, Nanosonics, Orthocell and Resmed up by less than one percent.

Yesterday's 18.9 percent best, 4D Medical, led the falls, down 13 cents or 6.9 percent to $1.76, with 21.3 million shares traded. Immutep and Mesoblast fell more than four percent; Actinogen, Micro-X and SDI were down more than three percent; Cynata, Impedimed, Imricor and Proteomics shed more than two percent; Compumedics and Polynovo were down more than one percent; with Clinuvel, Pro Medicus and Telix down by less than one percent.

DR BOREHAM'S CRUCIBLE: ARGENICA THERAPEUTICS

By TIM BOREHAM

ASX code: AGN

Share price: 32 cents; **Shares on issue:** 128,456,712; **Market cap:** $41.1 million

Chief executive officer: Dr Liz Dallimore

Board: Dianne Argus (chair), Dr Dallimore, Terry Budge, Dr Mark Etherton, Dr Jeannie Joughin

Finances (year to June 2025): revenue nil, net loss $7.17 million (previous deficit $5.48 million), cash of $10.56 million (down 33%)

Identifiable major holders: Neil Donald Delroy 3.4%, Perron Institute 2.8%, Litis Super 2.3%, Oofy Prosser (Drones family) 1.8%

Last week's savage reaction to Argenica's stroke drug trial results shows that investors didn't buy management's line that the data was "really, really positive - not just on safety, but the efficacy signals".

Argenica shares tumbled as much as 70 percent on the September 3 news, a response that CEO Dr Liz Dallimore concedes was "not super favorable".

Of course, the market is always right … until it's not.

Without question, the phase II effort hit its primary endpoint of safety and tolerability. While the study fell short of the secondary endpoint of efficacy, the therapy looks to be effective in an important, pre-defined patient subgroup.

"We understand not hitting that broad secondary endpoint has not met people's expectations," Dr Dallimore says.

But at this stage the program doesn't look a busted flush. As is typical with any trial data, the results contain plenty of nuances which we will examine below.

Hope for stroke victims

First - let's back up a bit.

One in four people will suffer a stroke in their lifetime. Of those, only 10 percent will recover completely. While 15 million people globally suffer a stroke each year - five million of them fatally – there's no effective treatment beyond thrombolytic drugs.

Argenica's reason for being is to commercialize its lead candidate ARG-007 as a neuro-protective agent for ischaemic (blockage) stroke patients.

It's also potentially relevant for other indications including moderate traumatic brain injury, hypoxic ischaemic encephalopathy, Parkinson's disease and Alzheimer's disease.

With strokes, the aim is to prevent infarction (brain cell death) that results from loss of blood flow caused by artery blockage (or separately, a bleed).

Argenica evolved from research carried out by the University of Western Australia (UWA) and the Perron Neuroscience Institute, and Argenica listed on June 11, 2021, after raising $7 million at 20 cents a share.

About ARG-007

Argenica's lead candidate is ARG-007, a cationic arginine-rich peptide.

Arginines are amino acids derived from one's diet and essential for producing proteins. ARG-007 is thought to have multiple mechanisms of action, preventing cascading cell deaths, including reducing oxidative stress and calcium influx.

When a vessel is blocked, the reduction in the blood flow affects the neurons around the vessels - with all kinds of nasty flow-on effects.

Up to the phase II trial, the company had undertaken supportive pre-clinical animal studies and a phase I safety trial of healthy volunteers. Animal modelling showed ARG-007 could reduce the total volume of cell death by 66 percent, 24 hours post stroke.

With only one intravenous injection, the drug's effect was still evident 28 days later.

About Seancon

Dubbed Seancon, the double-blinded, placebo-controlled, single-dose, phase II study enrolled 92 acute ischaemic stroke patients, about to undergo surgery to remove a blood clot (thrombectomy), at eight of 10 participating Australian hospital emergency departments.

The trial involved assessing stroke patients bought in an ambulance to a hospital. On arrival, they had a computed tomography (CT) scan to confirm they had suffered a large vessel occlusion stroke. The patients were randomized and treated.

Over 90 days, the patients' 'infarct' (brain cell) reduction was measured, along with adverse events and other quality of life measures.

The company targeted a recruitment period of 18 to 24, months, but the patients were enlisted in 12 months.

Safety first

The trial found ARG-007 to be “safe and well tolerated, with no statistically significant difference in treatment-emergent adverse events between ARG-007 and placebo groups”.

There was also no evidence of unwanted interactions with the thrombolytic clot-dissolving drugs.

“I know no-one gets excited about safety, but it [provides] the ability to do a lot because it gives clinicians the comfort to deliver the drug to a wide variety of patients,” Dr Dallimore says.

In the case of ARG-007, proving safety among the heterogenous stroke patient cohort was crucial.

The phase I trial examined healthy volunteers, while the phase II candidates were real-life patients with an average age of 72 years.

“Stroke patients are sicker and older and more things can go wrong,” Dr Dallimore says.

“It was really important to show our drug was safe in a phase II trial”.

Infarct, we did find some efficacy

At day three, ARG-007 did not show an overall treatment effect compared to placebo.

The company says “large variations in infarct volumes made it difficult to see an overall treatment effect.”

But - and it’s a big ‘but’ - the study found an average 15 percent infarct reduction “in a really critical” group accounting for about one-third of the patients.

The chair of Argenica’s clinical advisory committee and stroke neurologist Dr David Blacker explains: “Sometimes one artery can be blocked, but cross flow from another artery does the job.”

“It’s like putting a dam in a river: little tributaries will open up. “So, you can have a blockage, but if the ‘collaterals’ are good they will recover.”

ARG-007 wasn’t going to add much for this group that was doing okay.

Conversely, it wasn’t going to help patients with a blockage and no ‘tributaries’: a grim prognosis.

The 15 percent improvement was in a ‘Goldilocks’ group: patients with tissue lacking blood flow (under-perfused) that would improve if the artery was opened up.

Dubbed “slow collateral blood flow” candidates, these patients have more valuable grey matter to protect.

Dr Dallimore says the company’s “hypothesis” always was the drug would work best in the slow collateral cohort.

What’s next?

Good question.

Naturally, management is parsing the now-unblinded data to glean more information on the most efficacious doses and timing of delivery.

“We have quite a bit of additional data to unpack,” Dr Dallimore says.

This includes analyzing follow-on pharmaco-kinetic data from blood-sampling during the trial.

While nothing’s set in stone, this work could inform a follow-on phase IIb trial focusing on the ‘slow collaterals’.

The study would be “enriched” with the Goldilocks group but could still enroll a broader patient population.

“If we tweak the inclusion criteria or when the drug is delivered, we could still see benefit in the broader population,” Dr Dallimore says.

“We are trying to design the best experiment to answer the right questions.”

Dr Dallimore says achieving safety confers more trial options, such as enrolling patients from regional hospitals who are transferred to a central thrombectomy centre.

This means the drug is administered earlier, so the effect is stronger.

Petra Capital analyst Tanu Jain expects Argenica to complete data analysis by the end of 2025 and launch a phase IIb trial by the end of 2026.

Seeking the broader truth

Because the company had expected efficacy would be “difficult to clearly ascertain across a heterogeneous patient population”, the company set predefined patient subgroups.

In other words, it did not ‘data mine’ the results after the fact, to find the most flattering spin on things.

An obvious question is" "If the company suspected the 'slow collateral' patients would hit the efficacy hot spot, why did it recruit more broadly?"

Dr Dallimore reminds everyone that clinical trials are experiments.

"To design a good trial with suitable rigor, we needed to include a broader patient group," she says.

"If you ask one question, you will only get one answer. The idea of this study was to show it is safe in a broad population and then home in on the responding group."

What about the FDA?

Thinking ahead, Argenica had filed an investigational new drug (IND) application with the US Food and Drug Administration (FDA), to undertake a potential phase II/III trial.

In June, the FDA imposed a clinical hold on the application, for want of more safety data.

Dr Dallimore says the company hadn't planned to start the trial until mid-2026, pending the phase II results.

Wary of regulatory delays afflicting the FDA, the company got in early.

Of course, the timeline now has become more elongated anyway, given the likelihood of an intervening phase IIb trial.

Dr Dallimore says that to remove the clinical hold, the FDA has asked for three distinct in-vitro assays.

"Hopefully that should start in a month or so and we will have the data by the end of the year," she says. Then we will package that and put in front of the FDA."

Finances and performance:

Argenica has around $7 million of cash, with a $3.5 million to $4 million Federal Research and Development Tax Incentive yet to be banked.

Dr Dallimore says the phase II trial costs have been "pretty much paid for".

Argenica last raised equity in December last year, via a $12 million placement at 52 cents apiece, a then 18 percent discount.

In June this year, Argenica was awarded non-dilutive funding up to a total of $1.5 million, under a Federal Government program.

Argenica received the first $1 million up front, with $500,000 payable “if the project demonstrates high commercial potential”.

In the meantime, Argenica is scouring for non-dilutive trial funding.

Dr Dallimore compares the Goldilocks cohort market opportunity with the thrombolytic drug market, which is projected to be US$3.8 billion by 2030.

Since listing, Argenica shares have traded between 20 cents (early August 2021) and 94 cents (mid-January 2022).

Dr Boreham’s diagnosis:

Dr Dallimore describes the market’s reaction as “disappointing but not unexpected”, given the recent trial setbacks suffered by Opthea, Percheron and Syntara.

“It feels like the whole industry has had a hard trot of late,” she says.

“I’m just trying to get on the front foot and change the narrative. It’s disappointing we didn’t have that home run, but there are good positives and its pretty much does what a phase II is designed to do.”

Petra Capital’s Ms Jain describes the market response as “brutal” and argues the company still has a clear route to market.

Ms Jain says ARG-007’s clean bill of health bodes well for commercial prospects - even if the drug is approved initially for a narrow label.

“In stroke, doctors tend to use all tools in their box to treat a patient,” Ms Jain says. “As long as the drug is safe, they will likely prescribe it off-label even if it has modest efficacy as long as its pricing is not a barrier”.

In a musical vein, Dr Blacker likens the clinical trial process to a concertina.

“We start broad and bring it down,” he says. “Once we have proven in the smaller targeted population we can spring it back out again into the bigger group.”

In our view, ARG-007 prospects remain sound. But we agree with Dr Dallimore that many investors didn’t want to stay on the register for another two extra years or so.

Just as ‘time is brain’, time is money.

In concertina terms, Argenica needs to squeeze all it can from the Goldilocks group and not sound too many more discordant notes.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He never folds under pressure, but merely makes himself a small target when his editor is on the warpath.

POLYNOVO

Polynovo says its 64-patient Novosorb BTM diabetes wound trial led to faster closure in large surface area wounds, but the results were not statistically significant.

In 2022, Polynovo said it had enrolled the first of 138 patients in its randomized, controlled trial evaluating the safety and efficacy of Novosorb Synpath for chronic diabetic foot ulcers, with the primary efficacy endpoint the percentage of ulcers fully healed at 12 weeks (BD: Aug 10, 2022).

At the time, Polynovo chair David Williams said that surgeons had been using the company's Novosorb biodegradable temporizing matrix (BTM) for the treatment of diabetic foot ulcers, but it had developed Synpath as a specific product for diabetic foot ulcers and venous leg ulcers.

Today, Polynovo said an interim analysis of complete wound healing in all wounds at 12 months was observed in 66.7 percent of the 32 Novosorb BTM-treated wounds with negative pressure wound therapy standard-of-care treatment, compared to 56.5 percent of the 30 patients treated with standard-of-care alone, but that the results were "not statistically significant" ($p = 0.48$).

The company said there was a "significant decrease in the mean time to complete healing" for wounds larger than 10 square centimetres, with the Novosorb BTM group healing in 191 days compared to the standard-of-care group healing in 319 days, and "no significant difference observed in 12-month amputation rates".

Polynovo said the study positioned Novosorb BTM as a "useful device in the … treatment options for post-surgical diabetes-related neuropathic [and] neuro-ischemic wounds".

Polynovo acting chief executive officer Dr Robyn Elliott said "the exciting results of this study support the growing body of evidence that the Novosorb platform products are a significant addition to the treatment regime for diabetic related wounds and ulcers".

"A decrease of 'time to complete healing' of over four months is a huge benefit to the patient and health care system," Dr Elliott said.

Polynovo fell two cents or 1.4 percent to $1.44 with six million shares traded.

MTP CONNECT

MTP Connect says the Western Australia government has funded its WA Grant Excellence Service (Wages) to support researchers apply for Federal grants.

MTP Connect said it would conduct a three-year pilot program of the service, focusing on improving the quality of grant applications, including for the Federal Medical Research Future Fund, through "early intervention and support" and collaborative partnerships so that projects were prepared for grant opportunities.

The organization said the program would be led by Dr Tracey Wilkinson, with the Western Australia Life Sciences Innovation Hub, the Perth-based Synergy Health and supported by the Western Australian Future Health Research and Innovation Fund.

MTP Connect chief executive officer Stuart Dignam said the program would "provide a specialty research grant service designed to complement and deepen existing grant development activities … including those already provided under the WA Life Sciences Innovation Hub over the last few years".

"We know that access to funding remains the biggest challenge for researchers, start-ups and innovators especially at the early stage of innovation," Mr Dignam said.

"Our new Wages program will help upskill WA-based clinician researchers … early-to-mid career researchers, innovators and start-ups to improve their success in securing sovereign funding so they can take their medical innovations from bench to bedside," Mr Dignam said.

THE UNIVERSITY OF QUEENSLAND

The University of Queensland says it hopes to develop a saliva-based portable benchtop device to replace blood tests for “many diseases” including leukemia.

The University of Queensland said the project, led by its School of Mechanical and Mining Engineering’s Dr Dan Yuan, was in its early stages but had won the University’s up-to $50,000 Foundation Research Excellence Award.

The University said funding would go to preliminary data gathering ahead of developing a working micro-fluidic platform for immune cell isolation from saliva.

The University of Queensland said the device was based on “visco-elastic micro-fluidics”, the study of the movement and manipulation of tiny objects such as cells in liquid samples through microscopic channels.

Dr Yuan said the device required an external pump and microscopic high-speed camera to operate and observe, but she hoped the final device would be small, portable, and as simple as possible, to help remove the strain on hospital systems.

“Saliva testing is fast, painless and suitable for at-home, large-scale screening as we have seen with Covid-19 and flu kits,” Dr Yuan said. “The aim is to develop a test that avoids the need to come into hospital for a time-intensive check.”

“The non-invasive nature of saliva-based diagnostics will improve patient comfort and compliance, particularly in paediatric and routine screening populations,” Dr Yuan said.

“This could help enable early detection of diseases such as cancer, reducing mortality rates and healthcare costs,” Dr Yuan said.

“Cancer cells … such as leukemia cells … tend to be larger than normal cells, so by understanding the way tiny particles move in fluids like saliva, we can manipulate cells of different sizes into different channels, thereby detecting abnormal results,” Dr Yuan said.

WALTER & ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

WEHI says its Procap program will track prostate cancer patients from immigrant backgrounds to “better understand how cultural barriers impact their care and outcomes”.

WEHI said prostate cancer was the most common cancer in Australian men, but the reported incidence among immigrant men was lower, believed to be due to lower screening rates caused by language and cultural barriers.

The Institute said it would enroll 300 foreign-background patients with advanced prostate cancer in the next two years in the program, with participants to complete questionnaires related to healthcare experiences and quality of life during their treatment.

WEHI said Procap could also be used as a framework in other cancer types to track the experiences of immigrant women.

The Institute said patients would be selected through a multi-national registry that collated demographic, treatment and outcome data of patients with advanced prostate cancer.

WEHI said the project, titled ‘Using Patient-Reported Outcome and Experience Measures to Identify and Overcome Disparities in [culturally and linguistically diverse, or Cald] Patients with Advanced Prostate Cancer’, was supported by about $398,000 from Movember’s personalized prostate cancer care initiative.

WEHI’s Dr Arsha Anton said “clinical trials often don't include enough patients from culturally diverse populations, so very little is known about their experiences with prostate cancer, ability to cope with certain treatments and patient-reported outcomes”.

“We want everyone in Australia to feel assured that they will always get the best healthcare locally available, irrespective of cultural background,” Dr Anton said.

“This project is a huge step forward in bolstering that trust within multicultural communities,” Dr Anton said.

4D MEDICAL

4D Medical says Astrazeneca is the “pharmaceutical company” it will collaborate with in Brazil, and its Spectrum Medical contract is not “material in terms of revenue”.
On Monday, 4D Medical climbed as much as 52.1 percent on news that it had deals with the Royal Melbourne Hospital, Spectrum Medical Imaging and a “leading global pharmaceutical company”, with whom it would launch a screening program in Brazil for lung cancer screening and detecting incidental findings like coronary artery calcification and chronic obstructive pulmonary disease (BD: Sep 8, 2025).
Today, the company said the Spectrum contract was not material in terms of revenue but “important for being 4D Medical’s first contract supporting Australia’s National Lung Cancer Screening Program and is expected to grow significantly over time”.
4D Medical fell 13 cents or 6.9 percent to $1.76 with 21.3 million shares traded.

ANTERIS TECHNOLOGIES GLOBAL CORP

Anteris says it has postponed its special meeting to approve the ASX Listing Rule 7.1 waiver, for a second time, again to “facilitate broader participation”.
Last week, Anteris said it had postponed its special meeting to provide shareholders “additional time to vote in order to facilitate broader participation”, having initially been scheduled for 5pm US Central Time on September 4, 2025 or September 5, 2025 at 8am (AEST). (BD: Sep 4, 2025).
Last month, the company said it had a “waiver from ASX Listing Rule 7.1 to issue new securities without obtaining security holder approval” (BD: Aug 8, 2025).
Anteris said ASX Listing Rule 7.1 restricted “listed entities from issuing securities in excess of 15 percent of their issued share capital without security holder approval over a 12-month period unless an exception applies”.
Today, the company said the online meeting, scheduled for 5pm US Central Time on September 11, 2025 at 5pm US Central Time, or September 12, 2025 at 8am (AEST), would be held on September 18, 2025 at 5pm US Central Time, or September 19, 2025 at 8am (AEST).
Anteris was up 38 cents or 5.45 percent to $7.35.

PRESCIENT THERAPEUTICS

Prescient says investors will vote to grant 12,942,721 options to chair Dr James Campbell and directors Dr Allen Ebens, Melanie Farris, Dr Ellen Feigal and Dr Gavin Shepherd.
Prescient said shareholders would vote to issue 5,257,573 options to Dr Campbell, 2,628,787 options each to Dr Ebens and Ms Farris, and 1,213,787 options each to Dr Feigal and Dr Gavin Shepherd, as part of their remuneration.
The company said the options would vest in four equal yearly tranches and would be exercisable at the higher of 10 cents each or a 45 percent premium to the 10-day volume weighted average price up-to and including the date of grant.
Prescient said its shareholders would vote to adopt its remuneration report, re-elect Dr Ebens, elect Ms Farris, approve its executive option plan and issue of 150,000,000 equity securities, ratify placement shares and options, approve its 10 percent placement facility, and approve amendments to the company constitution.
The meeting will be held at FB Rice, Level 33, 477 Collins Street, Melbourne on October 14, 2025 at 11:00am (AEDT) and on-line.
Prescient was unchanged at 4.1 cents.

MESOBLAST

Gregory George, and G to the Fourth Investments say they have increased their Mesoblast holding from 243,495,998 shares (19.13%) to 267,021,132 shares (20.90%).
The Tampa, Florida-based Mr George said the shareholders included James Goerge, Grant George, Citicorp and JP Morgan; and that the shares were acquired between February 28 and September 11, 2025, with the single largest purchase 2,000,000 shares for $3,046,478.5 or $1.52 a share.
Last week, Mesoblast said it had an up-to $US50 million ($A75.1 million) convertible note subscription option with Surgcenter's Gregory George and William Gueck, principals in the Baltimore, Maryland-based Surgcenter and Mesoblast investors, who would receive a commitment fee of $US100,000 ($A150,120) and two million warrants over two million shares, or 200,000 Mesoblast American depositary receipts (ADRs), for entering in the convertible note option, and a further three million warrants should Mesoblast exercise the option (BD: Sep 4, 2025).
Mesoblast fell 11 cents or 4.7 percent to $2.21 with 5.3 million shares traded.

ADALTA

New Life Sciences, Bergen Global and Eugene Tablis say they have reduced their holding in Adalta from 147,023,550 shares (11.13%) to 88,925,648 shares (6.73%).
The Boca Raton, Florida-based New Life Sciences, Bergen Global Opportunity Fund and Eugene Tablis said that they sold 58,097,902 shares for $222,306 or 0.38 cents a share.
Adalta was unchanged at 0.3 cents with 1.2 million shares traded..