# Biotech Daily

Friday September 12, 2025

*Daily news on ASX-listed biotechnology companies*


# 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.

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.

They include 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.***