Biotech Daily

Friday November 20, 2026

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Arovella Therapeutics

By TIM BOREHAM

ASX code: ALA

Share price: 4.6 cents

Shares on issue: 1,208,851,853

Market cap: $55.6 million

Chief executive officer: Dr Nicole van der Weerden

Board: David Williams (chair), Dr van der Weerden, Dr Michael Thurn, Mark Diamond

Financials (September quarter 2026): receipts nil, net cash outflows $2.7 million, cash balance $11.6 million (before $4.0 million Federal Research and Development Tax Incentive received in October), quarters of available funding: 4.2

Identifiable major shareholders: Biotech Capital Management (formerly Merchant Funds Management) 10.72%, Richard Mann 5.67%, Ajava Holdings 2.48%, Blackburne Capital Pty Ltd 2.26%, Legacy Asset Holdings Pty Ltd 1.85%

With drug development, it's easy to forget about the patients amid the Powerpoint presentations on the niceties of clinical trial design and hype about billion-dollar addressable markets.

But Arovella Therapeutics' new CEO Dr Nicole van der Weerden isn't making that mistake as the company develops a refined form of chimeric antigen receptor T-cell (CAR-T) therapy.

At one of her first investor outings since becoming permanent CEO on November 4, she displayed a picture of 21-year-old, US patient Emily Whitehead, the first paediatric cancer patient to receive a CAR-T cell therapy for her blood cancer.

Cancer-free after 13 years, Emily is “the poster child for what CAR-T can achieve”.

Blood cancer patient Sam Neill needs no introduction. The late New Zealand actor underwent an undisclosed experimental CAR-T treatment in a clinical trial and remained cancer free.

He died in mid-July aged 78, from complications (pneumonia) related to an infection from “some of the really harsh therapies” patients need to undergo before receiving CAR-T treatment.

Cell therapy refers to extracting human cells from a patient or donor and improving them so they can fight disease more effectively.

Arovella is seeking to overcome the problems of CAR-T therapies by involving invariant natural killer (INKT) T-cells.

INKT cells are a rare variant of T-cells – and one of the body’s strongest immune cells.

“Our goal is to improve patient access and bring those cell therapies earlier in the treatment cycle,” Dr van der Weerden says.

Arovella aims to hit its drug targets

Hitherto Arovella’s chief operating officer, Dr van der Weerden was attracted to Arovella as a “structurally differentiated, next generation” cell therapy developer.

The company’s flagship program, ALA-101, targets a blood cancer marker called CD19 (see below). Last month, the company dosed its first patient in a first-in-human, phase I trial.

As with many ASX biotechs, Arovella has a convoluted history and is on its third name.

The company’s origins date back to Eastland Medical, which listed in 2001.

Eastland was developing a retractable syringe and then a sublingual malaria treatment. Eastland morphed into Suda Pharmaceuticals in 2012 to develop a spray-based oral drug delivery platform, called Oromist but things did not go as planned.

Biotechnology entrepreneur Paul Hopper took over as executive chair in 2019, with the charter of changing the company’s direction to cancer cell therapies.

He hired Bioscience Managers investment guru Dr Michael Baker as CEO.

In June 2021, Arovella acquired its INKT cell platform from Imperial College London.

In October 2021, the company changed its name to Arovella, which derives from arrow (as in targeted drug delivery) and novel (as in new therapies).

Mr Hopper quit the board in June 2022, with well-known biotech figure Dr Thomas Duthy becoming chair.

Dr Duthy resigned in July 2025.

In early 2026, a ginger group headed by biotech (and agriculture) man-about-town David Williams launched a board challenge, seeking to sharpen the company's commercial focus.

Records fall in 'board refresh'

In the May 4 'board refresh' Dr Baker quit, as did directors Dr Andrew Nash, Dr Deborah Barton and Dr Mike Perry.

The former CEO of Avita Medical, Dr Perry had been on the board for a mere five working days – a record short stint.

Joining the board were Dr Michael Thurn (former CEO of motor neuron disease drug developer Neurizon), Mark Diamond (former CEO of Antisense Therapeutics, now Percheron Therapeutics) and Mr Williams (who became chair).

A few days later Dr Van der Weerden became acting CEO, having been chief operating officer since 2023.

With a Doctor of Philosophy in biochemistry and a Master in Business Administration from Melbourne Business School, Dr Van der Weerden spent 18 years at Hexima, including as CEO. She was hired by Dr Baker, with whom she had worked in the past. They also completed their doctorates at the same time.

At Hexima, Dr Van der Weerden led a team that that discovered and developed pezadeftide for onychomycosis (toenail fungus). But the phase II study failed.

Dr Baker now heads fellow cancer drug developer Percheron.

What's the problem?

CAR-T therapies have involved the autologous approach of taking the patients' own blood cells and genetically modifying them in a laboratory with the 'supercharged' T-cells.

They are then tested for safety and re-infused into the patient.

"That takes three to four weeks and it's very logistically demanding," Dr van der Weerden says.

“You need specialized treatment centres to do the collection and … it's usually only major hospitals in big cities that can administer this type of therapy.”

Manufacturing and supply chain costs are very high, because the process never was set up for just one patient.

“Our platform is about being able to take this rare powerful immune cell and produce commercially scalable, very potent anti-cancer cells.”

She adds that patients on CAR-T can be compromised by the disease and previous treatments.

“Not all patients can have their cells manufactured, because they are just not fit enough.

“Some patients just unfortunately don't make it to receive their treatment.”

What’s the solution?

While Arovella didn’t invent INKT-cells - nature did - the company’s smarts are tied up in a multi-step manufacturing process that can be done in numerous ways.

Around 10-15 percent of the body’s immune cells are ‘natural killer’ (NK) cells and around 70 percent are ordinary T-cells.

Of the NK cells, NKTs make up only 0.1 to 1.0 percent.

Arovella’s approach is predicated on ‘off-the-shelf’ manufacturing, with the doses frozen until needed.

“We can produce up to hundreds of doses per batch and that material is then ready and waiting. When the patient's identified they can be dosed within a week,” she says.

Dr Van der Weerden says that unlike T-cells, INKT-cells are naturally allogeneic.

“You can’t take a T-cell from a healthy donor to a patient, because that cell will recognize the patient as foreign and attack the patient's cells (graft-versus-host disease).”

Firing the starter’s gun on ALA-101

In late October, the company dosed its first patient in the phase I trial, having received US Food and Drug Administration investigational new drug (IND) approval in January 2026.

The two-part study begins with a dose escalation trial of nine to 12 patients and then a phase Ib expansion, at five Australian sites with a potential New Zealand site, as well.

The trial will enrol adults with relapsed and refractory CD19-positive blood cancers, mainly non-Hodgkin's lymphoma (various subtypes) and leukaemias.

Patients also undergo lymphodepletion (conditioning chemotherapy) and then receive a single dose of ALA-101. They then are monitored for the next two years.

If required, they go into a long-term follow-up study.

Dr van der Weerden says the adaptive “backfill” design of the study will enable the trial to dose additional patients at safe levels.

Arovella plans to take the optimum dose into a phase II study, targeting around 46 patients.

The company was encouraged by earlier mouse work in which the rodents were infused with CD19-expressing, aggressive B-cell acute lymphoblastic leukaemia cells.

In the jive with ALA-105

Arovella’s second product, ALA-105 is pitched as a similar, off-the-shelf product for solid tumors.

ALA-105 is based on technology licenced from China’s Sparx Group in October 2023, targeting the protein Claudin18.2 (CLDN18.2).

ALA-105 deploys a different lentivirus carrying the genetic material, to make a CAR-T targeting CLDN18.2.

The company is banking on the ability of INKT-cells to block cells that promote tumor survival and to release cytokines to stimulate an immune response.

“Claudin 18.2 is a validated target for gastric and pancreatic cancers and several other cancer indications,” Dr van der Weerden says.

“We think our ALA-105 addresses key challenges around efficacy and the ability for these cells to infiltrate into tumors and have multiple ways to target the tumor cells.”

In late October, the company reported first proof-of-concept in-vivo data showing “a really nice clearing” of the cancers in an advanced gastric cancer model in mice.

The CAR-T-treated control group had some benefit, but eventually succumbed to the tumors.

In the ALA-105 treated cohort, five of the seven mice showed no signs of tumors by the end of the study.

In search of the Holy Grail

Regulators have approved only a handful of CAR-T therapies, all but one for blood cancers and all of them autologous.

The outlier is Karsten's satri-cel (satricabtagene autoleucel) for gastric cancers, approved by Chinese authorities.

Dr van der Weerden says satri-cel's efficacy is "not great", providing two extra months of progression-free survival.

"At $500,000 a dose that's going to be a hard sell," she says.

"I'm confident we will be able to outperform that with an off-the-shelf product with a lower cost of manufacturing."

While CAR-T developers abound, only about four are delving into INKTs.

This includes Japan's Brightpath Therapeutics, which seeks to derive the INKTs from pluripotent stem cells.

Dr van der Weerden claims Arovella is the most advanced INKT player.

Beyond cancer, the auto-immune side opens up opportunities in diseases such as lupus, myositis, systemic sclerosis and stiff person's syndrome.

Stiff person's syndrome? It's a rare neurological disorder that causes severe muscle stiffness, rigidity, and painful muscle spasms

And – yes – we have a celebrity sufferer: Celine Dion.

Finances and performance

Arovella held September-end cash balance of $11.6 million following September quarter cash outflows of $2.7 million.

In October, the company pocketed a $4.03 million Federal Government Research and Development Tax Incentive, taking the pro-forma balance to $15.63 million.

In February last year, Arovella raised $15 million at 12.5 cents apiece. Holders also received options on a one-for-three basis, exercisable at 15 cents by May 24, 2027.

While successful, the raising followed a botched attempt a month earlier to raise $20 million at 17 cents a share. Arovella shares tumbled after news that a local private investor had reneged on a $15 million commitment.

The company has enough funds for the initial ALA-101 phase, but not for all 46 patients.

Over the last 12 months Arovella shares have sauntered between 10 cents on February 3, 2026, and 4.7 cents on October 6 this year.

Over the last 12 months the stock has lost around 40 percent of value.

In the Arovella era, the shares bottomed at around 2.5 cents in November 2022 and peaked at 20.5 cents in November 2024.

Dr Boreham's diagnosis:

Other parties have developed an alternative approach, called in-vivo-CAR by which the CAR-T-cells are 'manufactured' in the person.

In other words, their blood doesn't have to be removed and then restored.

In theory, Arovella's method risks being superseded.

Dr van der Weerden says it's still early days and in-vivo-CAR's safety has not yet been determined

"In-vivo-CAR is a really interesting approach that addresses some of those logistics and manufacturing issues," she says.

"They certainly haven't demonstrated durable efficacy."

She says that - thanks to CAR-Ts - "people now use 'cure' and 'cancer' in the same sentence, which was unheard of 10 years ago".

As the company notes, three approved CAR-T drugs for blood cancers turned over $US4.7 billion in 2025.

In the current skittish market, investors increasingly want tangible results.

With the preliminary phase I results due early next year, at least they won't have to wait long for the next instalment.

After a decent summer break and we'll be there!

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His summer break is nearly there - just 14 days away, but we're not counting … are we?