Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Avecho Biotechnology

By TIM BOREHAM

ASX Code: AVE

Share price: 2.3 cents

Shares on issue: 3,863,725,873

Market cap: $88.9 million

CEO: Dr Paul Gavin

Board: Dr Greg Collier (chair), Dr Ross Murdoch, Kathy Connell (Matt McNamara resigned in May)

Financials (March quarter 2026): sales revenue nil, receipts $184,000, cash outflows $887,000, cash balance $4.34 million.

Major identifiable shareholders: Paradyce Pty Ltd 9.5%, Ms Chunyan Niu 5.1%, Rosscope Pty Ltd (Ross Copeland family account) 2.45%

Avecho CEO Dr Paul Gavin says he hasn't slept in weeks, "which is ironic given we're running a phase III insomnia trial".

He adds: "Waiting on an interim analysis result is torture. I don't recommend it."

The pain proved to be worthwhile, with the success of the trial to date contrasting starkly to the late-stage misfortunes afflicting ASX listed drug developers.

Only a few days earlier Cynata Therapeutics – which we covered last week – came up short in its two key stem cell trials.

“Biotech sentiment is really low right now,” Dr Gavin says. “There's been a sequence of unwanted outcomes that nobody's wanted. Investors are hesitant to invest and the sector has been needing a win.”

While Avecho’s results last week were interim, with the data remaining blinded, Dr Gavin says the event was the trial breakthrough the sector needed.

“This does not come around every day. It significantly de-risks the remaining phase III trial,” he says.

“While the trial still needs completion, we're moving forward with the assumption that the product works for insomnia.”

So, what happened?

Avecho has been trialing its proprietary soft gel cannabidiol (CBD) to manage sleeplessness.

To improve patentability, the company has added its proprietary tocopheryl phosphate mixture (TPM) to improve delivery.

The pivotal, 519-patient local trial is aimed at winning Therapeutic Goods Administration approval as an over-the-counter pharmacy medication (see below).

“This is the largest randomized, placebo-controlled CBD insomnia trial anywhere in the world,” Dr Gavin says.

(In 2023, Cann Group’s 257-participant trial of CBD for sleep disturbances showed no significant differences on its endpoints compared to placebo.)

On June 24, this year, the company proclaimed that an independent data monitoring board (DMB) had recommended the trial continue without alteration.

This was based on an interim analysis of the first cohort of 244 patients.

Dr Gavin says the DMB could have recommended the study expand recruitment to improve statistical powering or abandon it on ‘futility’ grounds.

The experts also could have recommended trial cessation on the grounds the drug worked so well that the study could be curtailed. But let’s not get too carried away.

Dr Gavin says the result “provides confidence that the product is working, which is very exciting both for the company, our partner, and our shareholders.”

Three decades of thrills

So where do we start with Avecho's colorful evolution?
Then known as Greenchip Development Capital and later Phosphagenics, the company listed in August 1993.

The company pivoted to biotechnology in 2004, with its activities based on the aforementioned TPM tech.

Effectively phosphorylated vitamin E (hence Phosphagenics), TPM enhances the solubility and absorption of certain drugs and nutrients.

The company's initial quest was to crack the difficult transdermal delivery via patches, but its focus expanded to oral and dermal delivery using gels and injectable products.

On home shopping channels, then CEO Dr Esra Ogru enthusiastically spruiked Phosphagenics' personal care products, such as cellulite and stretch mark busting creams.

In late 2014, Dr Ogru was gaoled for six years (two years non-parole) for her part in a $6 million fraud against the company. She was released from prison in 2016.

Post the Dr Ogru scandal, the company undertook a "systemic process to rebuild the foundations of the business, restore difficult legacy issues and set the stage for us to rebuild confidence and attract new partners and commercial opportunities."

In late 2018, Phosphagenics shares lost most of their value after the company lost a $US300 million compensation claim. This pertained to a research and licencing deal to enhance delivery of daptomycin, the world's most-used injectable antibiotic.

Avecho got into cannabis – so to speak – with two supply deals in mid-2020.

Previously the company's chief scientific officer, Dr Gavin became CEO at around the same time.

About the trial

The subjects had been dosed for eight weeks, with one third of them receiving 75 milligrams of CBD and one third 150mg, with the unlucky remainder getting the placebo.

The participants measured their sleep via the self-reported Insomnia Severity Index, or the Subjective Sleep Efficiency (the amount of time they are asleep).

Because the trial was – and remains - fully blinded, the participants, investigators and the company did not know to which arm the patient was assigned.

Only the DMB members had privy to the data and did not explicitly say: 'hey, it's working!'

But the ‘carry on as is’ recommendation speaks volumes.

“In effect, the DMB is confirming there is a difference between CBD and placebo and [affirms the] patient numbers required to ensure a high level of statistical significance,” Dr Gavin says.

The DMB consisted of an ‘unblinded’ statistician – nothing to do with drinking habits – an international sleep expert and an expert pharmacologist, to monitor safety.

Speaking of which, there were no adverse events or other safety concerns from ingesting the pills, which do not contain the psycho-active element tetra-hydro-cannabinol (THC).

“In practical terms for the company this was a binary event for our insomnia program,” Dr Gavin says.

“Either the drug was proven to be working in the interim analysis - or it wasn't.”

He said the trial needs to meet only one of the primary endpoint measures. “It doesn’t matter which one and we won’t know until the end of the trial,” Dr Gavin says.

In designing the trial, the company was aware that the ‘placebo effect’ could be a trial “killer” in an insomnia study.

“Our protocol has multiple mechanisms to limit the damage of the placebo effect and we were really comfortable with all of these design aspects in place.”

Safety first

Dr Gavin dubs insomnia as a “huge clinical indication”.

At any time, 10-30 percent of the populace will be counting sheep.

Of course, other remedies are available, such as sleeping tablets. “The insomnia market is large and growing and there are a number of products vying for this market,” Dr Gavin says.

“But Avecho has now a safety gap that we can very explicitly exploit.”

The existing drugs have unwanted side effects including dependence, tolerance, withdrawal symptoms and next day impairment and overdose toxicity.

“You cannot kill yourself with CBD so there's no overdose risk there.”

While there’s no approved cannabidiol products on market, many insomniacs will resort to their friendly local dealer – or gain a prescription under the TGA’s authorized prescriber scheme.

Authorized doctors can administer unapproved drugs, in cases where other therapies have fallen short.

As has been well reported, the TGA is concerned about lax prescribing from telehealth providers and de facto recreational use of medical cannabis.

In 2020, the agency introduced an over-the-counter mechanism, by which low-dose CBD drugs, not containing THC, could be prescribed by pharmacists.

To date, no company has adopted this route because the requisite clinical proof and quality is very high.

Avecho intends to be the first to win over-the-counter (OTC) approval.

The company is not acting on a whim.

In March last year, Avecho signed over exclusive local rights to Sandoz, the world's biggest generic drug maker, in a 10-year development and licencing deal.

Dr Gavin says it's telling that a generics player saw the potential of the OTC market with a branded drug.

Avecho received an upfront payment of $US3 million ($A4.8 million), with $US16 million of potential milestones prior to commercialization.

The interim result did not unlock any milestone payments.

Avecho is entitled to a tiered royalty of 14-19 percent on net sales.

Finances and performance:

Avecho has about $6.2 million of cash on a proforma basis.

In the March quarter the company had cash outflows of $887,000, reflecting $493,000 of research and development expenditure.

Dr Gavin stresses the company does NOT intend to carry out a capital raising.

So, if investors want to be in on the story, they need to buy on market rather than wait for a discounted raising.

Given the company costs the rest of the trial at $15 million, how will it fund the dosing of the 300-patient cohort?

The answer lies in further licencing deals to cover other geographies.

"There are a number of people at the table," Dr Gavin says.

“Now that we have the commercial validation and the interim data, expect licencing discussions to ramp up.”

Sandoz has the first right of refusal to match another party’s deal terms.

Dr Gavin says while the Australian OTC sector is “commercially lucrative”, it remains one of the smaller global pharmaceutical markets.

“It's still a very important benchmark as you can extrapolate the terms that we got for the Australian market over to the overseas deals.”

Over the last 12 months Avecho shares have risen steadily from 0.04 cents on June 30 last year, to Tuesday’s peak of 2.4 cents. Over the last five years the stock has traded as low as 0.02 cents (October 2024) and 2.2 cents (May 2022).

What’s next?

Avecho is ready to dose “in coming months” at existing sites.

Pending the aforementioned partner funding, the company hopes to introduce 10 additional sites.

“Then we can smash through the remaining patients in about 12 months,” Dr Gavin says.

“We learned a lot of lessons about the recruitment rate and … we are very comfortable these 300 get [dosed] very quickly.”

As a guide, one site in Sydney has enrolled 100 participants between July last year and February this year.

And did someone mention the US and Trump?

Indeed, the Orange Man has signed an executive order that facilitates medical cannabis research in a number of ways.

One key measure is potential approval on the back of one phase III study, rather than two.

Avecho intends to engage with the US Food and Drug Administration this year.

“In the past, we thought the FDA would be a lower priority. But after President Trump signed [the executive order], all that has changed.

“My US regulatory firm has advised me I need to get in front of them as quick as possible, because there may be a scenario where we can [win approval] much quicker than we had been anticipating.”

The company expects the phase III study to complete in 2027 or early 2028, after which it will present a dossier to the TGA.

Dr Boreham's diagnosis:

Dr Gavin says the interim results were a "huge sigh of relief for everyone".

Veteran partakers of the Devil's lettuce might be puzzled about the sophistry surrounding the insomnia study.

After, all there's about 1,000 years of real-world evidence that pot makes you sleepy (albeit with THC).

But the truth is that in order for regulators to approve a cannabis drug, applicants need to pass the highest burden of proof.

Dr Gavin says the safety and efficacy signals from the interim results mean the company can take one aspect for granted.

That is – the drug works.

"The insomnia market is large and growing and there are a number of products vying for this market," Dr Gavin says.

"But Avecho has now a safety gap that we can very explicitly exploit."

"If we are successful, we'll have the first mover advantage for the local [over-the-counter] market that could be worth hundreds of millions a year."

Dr Gavin describes completing the trial as "procedural" more than anything.

"This is a hugely exciting time for the company and so I'll be running around doing a victory lap for the next few months."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has an open mind on CBD as an insomnia cure but will need to sleep on it.