Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Amplia Therapeutics

By TIM BOREHAM

ASX code: ATX

Share price: 14.5 cents

Shares on issue: 513,312,014

Market cap: $74.4 million

Chief executive officer: Dr Chris Burns (co-founder)

Board: Jane Bell (chair), Dr Burns, Dr Warwick Tong, Dr Robert Peach, Brett Carter

Financials (June quarter 2026): receipts nil, net cash outflows $3.9 million, cash balance $24 million, quarters of available funding 6.2

Major identifiable holders: Platinum Investment Management 7.8%, Acorn Capital 8.1%, Pengana Capital 5.6%, Blueflag Holdings (Allan Moss) 4%

As with the rag trade, drug developers are subject to the whims of fashion and the latest trend is for them to diversify their clinical programs.

Given the number of unsuccessful late-stage drug trials, that's an understandable 'fashion statement': more so than paying a fortune for ripped jeans or pants that stop at the ankle.

Pancreatic cancer drug developer Amplia is the latest party to hedge its bets beyond its original remit, this month inking a collaboration with Eli Lilly.

A collaborative study will combine Amplia's lead compound narmafotinib (AMP-945) with an Eli Lilly Kras inhibitor, which are all the - er - fashion at the moment (see below).

The company is also carrying out an ovarian cancer study via a third party.

Pancreatic cancer remains Amplia's lead program.

We would like to say that there's been huge strides in treating the disease. But unlike with many other cancers, the dial hasn't moved.

Pancreatic cancer still remains the deadliest of tumors, partly because it is usually detected late.

Around 70,000 US patients and 5,000 Australians are diagnosed each year.

This week, legendary Australian entertainer Johnny Young succumbed to the disease, aged 79. Only 12 percent of patients will survive five years, compared to 21 percent for liver cancer and 23 percent for lung cancer.

"Patients clearly need better treatments," says Amplia CEO and co-founder Dr Chris Burns.

Highly promising, as a matter of FAK

Amplia is all about its pipeline of focal kinase inhibitors (FAKs) for cancer and fibrosis.

AMP945 was discovered at the former Cancer Therapeutics Cooperative Research Centre and works by suppressing the FAK protein, as over-expressed in several cancers.

The suppression makes the tumors more responsive to chemotherapy.

Amplia dubs AMP945 as a "highly potent and selective inhibitor of FAK".

Dr Burns describes a "one-two punch" effect: "There's a punch on the area around the tumor … and there's a punch on the cancer cell itself.

"When you combine that with chemotherapy, you get this profound effect where the cells die and the tumor shrinks."

Amplia stems from Innate Immunotherapeutics, which developed a multiple sclerosis drug but stumbled at phase II stage.

Innate eventually acquired the FAK program via Amplia, owned by parties including Telix Pharmaceuticals founder Dr Chris Behrenbruch and Dr Burns.

Innate changed its name to Amplia in 2020 and Dr Burns became its CEO in December 2022.

On trial

In mid-2025, investor interest in Amplia was piqued by the first of several stellar results of the company's Ib/IIa 'Accent' trial, at local and South Korean sites.

The open-label study combined narmafotinib with the common chemotherapies gemcitabine and Abraxane.

The company presented the "mature" data to the American Association of Cancer Research in April this year.

The highlight was five out of 64 patients – 7.8 percent – achieving a 'complete response' compared with just 0.2 percent for chemo alone.

(A complete response means all visible and detectable signs of the disease have disappeared).

The overall response rate was 36 percent, or 42 percent including unconfirmed responses.

Amplia also reported a two-month improvement in both median overall survival and progression-free survival, to 11.1 months and 7. 7 months respectively.

This compared with 8.5 months and 5.5 months for chemotherapy alone.

What's next?

Narmafotinib was administered for only 12 days of each 28-day cycle.

To build on the "compelling" data, Amplia has initiated a trial dubbed 'Accent Mini', examining daily dosing for advanced pancreatic cancer patients.

A safety lead-in to a planned phase IIb effort, the trial is enrolling 12 newly diagnosed patients in two equal dosing cohorts, at up-to four Australian sites.

"Designed in alignment with FDA feedback, the study will form the first stage of a registrational study in this indication, given the high existing unmet need for innovative treatments," the company says.

As well as assessing safety and all that jazz, the study will look for efficacy and measure biomarkers and fibrosis. The first patient is due to be dosed in September.

"To date narmafotinib has shown no significant tolerability burden over chemotherapy alone, and we have observed a range of compelling efficacy signals across responses and survival," Dr Burns says.

“This has been achieved with only an intermittent dosing schedule, giving us confidence that moving into daily dosing may further enhance the therapeutic potential of narmafotinib.”

Due to start by July 2027, the follow-on phase IIb trial will hone the optimum dosage for a pivotal phase III study.

Amplicity trial is now on mute

Amplia was running a separate trial called Amplicity, combining AMP945 with the chemotherapy cocktail regime Folfirinox (folinic acid or leucovorin, fluorouracil or 5-FU, irinotecan and oxaliplatin). But no longer.

In April, the company halted recruitment after three “dose limiting toxicities” emerged. Crucially, these problems related to Folfirinox and not AMP945. But investors still wiped 44 percent off Amplia’s share price.

The company said five patients remained on the study and would continue to get the combination treatment.

Folfirinox is one of the main chemotherapy regimes for pancreatic cancer.

While widely used in the US and Europe, it’s an “aggressive”, toxic drug and thus more suited to fitter patients.

Dr Burns said other therapies such as Kras inhibitors (see below) have emerged since Amplia started the trial.

“Where does that leave a highly toxic chemotherapy?” asks Dr Burns.

Ovarian cancer collaboration

In alliance with the Australia New Zealand Gynaecological Oncology Group (ANZGOG), Amplia has launched an ovarian cancer trial called Prrose.

This unwieldy acronym derives from the terms ‘platinum resistant/poor response’ and ‘ovarian serous [relating to a serum] surgery’.

“Ovarian cancer is another cancer that's highly fibrotic, with a clear involvement of the signaling pathways that we block,” Dr Burns says.

The investigator-led study road-tests the narmafotinib-chemotherapy combination on patients with high-grade serous ovarian cancer, who have responded poorly to initial chemotherapy.

The small study will enroll about 20 patients across Australian and New Zealand sites.

Amplia funds the trial on what Dr Burns dubs as “mates’ rates”.

The trial is led by Monash Health’s medical oncologist Dr Gwo Yaw Ho and will assess whether adding narmafotinib to the mix can improve response rates and increase the number of patients eligible for life-saving surgery (by shrinking the tumors).

“There is a compelling biological rationale for FAK inhibitors in ovarian cancer and the company has pre-clinical data further supporting the clinical potential in this indication.”

In May last year, the FDA granted accelerated approval for the Nasdaq-listed Varastem Inc’s ovarian cancer treatment, based on a FAK inhibitor.

Nothing Kras about these inhibitors

On August 4, Amplia announced a collaboration with Eli Lilly, to evaluate narmafotinib (AMP945) in combination with the latter’s Kras inhibitor called olomorasib.

Kras stands for – wait for it - Kirsten rat sarcoma viral oncogene homolog.

Kras-es are a hot area of cancer research but clinicians suspect they become less effective as patients develop resistance.

A Kras mutation is a genetic error that locks the Kras protein in a permanent "on" position, driving uncontrolled cell growth. The Kras inhibitors are thought to be ‘keys’ that overcomes these obstacles.

The phase Ib/IIb first-line trial will target non-small cell lung cancer (NSCLC). Amplia will carry out the study at local and US sites, with an expected kick-off in 2026.

Eli Lilly currently is undertaking two second-line phase III studies in NSCLC.

Amplia notes that around 50 Kras trials are in progress globally and a handful of Kras drugs have been approved.

However, the drugs can have severe side effects and “treatment-emergent resistance is commonplace”.

Dr Burns says the Eli Lilly collaboration is about proving that narmafotinib can make a Kras inhibitor work better.

“That doesn't necessarily mean that we're shifting gears to lung cancer,” he says.

“Hopefully it’s showing the combination can work in lung cancer. But the mechanisms of resistance are the same in pancreatic cancer and the same in colo-rectal cancer.”

Amplia funds the circa 55-patient trial, partly from resources diverted from the Amplicity study. Eli Lilly supplies their drug and know-how.

Finances and performance

Amplia recorded net cash outflows of $3.9 million, with $3 million of expenditure on research and development (mainly via a contract research organization).

The company finished the quarter with cash of $24 million.

Dr Burns said the company was eyeing an Asia-Pacific licence to bring in extra funding.

“Running a phase III study in pancreatic cancer is not going to be cheap so we're … trying to identify the best path forward and the most efficient way to get critical data.”

The trial is likely to cost somewhere between $50 million and $100 million.

In July Amplia raised $27.5 million in an institutional placement and share purchase plan, at 23 cents apiece (a 19 percent discount).

Over the last 12 months Amplia shares have ranged between 26.5 cents on April 1, 2026 and 10.5 cents on June 16.

Amplia shares peaked at 35 cents on July 11, 2025, having hit a low of five cents on May 30 of that year.

The initial news of the Accent complete responses spurred the dramatic rise.

Amplia underwent a 10-to-one share consolidation in 2018.

Amplia has enjoyed strong institutional support, led by Platinum Investment Management with a nine percent holding. Former Macquarie Bank supremo Allan Moss also graces the register.

Dr Boreham’s diagnosis:

Dr Burns said the pancreatic cancer complete responses “got a lot of people interested in the work we are doing”.

He said two other drug developers had therapies with a similar mechanism of action.

“Neither of them is working in pancreatic cancer, but one of them had their drug approved in a rare form of ovarian cancer,” he said.

“So, the target's validated from a clinical perspective and also by the [the FDA].”

While pancreatic cancer remains the company’s lead program, ovarian cancer and Kras inhibitors for broader indications are potentially bigger markets.

Amplia reckons pancreatic cancer is worth $US3.2 billion a year, compared to $US5.8 billion for ovarian cancer and $US7.8 billion for Kras inhibitors (by 2035).

In the high-stakes drug development game, investors can skew the odds in their favor by backing someone who has done it before.

Dr Burns co-developed the myelofibrosis drug Ojjaara (momelotinib or CYT387) with Professor Andrew Wilks (now of Synthesis Bioventures).

Ojjaara ended up in the hands of Glaxosmithkline in 2022, in a $US1.9 billion deal. The FDA approved Ojjaara in 2023 – only the third time the agency approved an Australian grown drug.

(Stop scratching your heads: the others were Hatchtech's Xeglyze for head lice and Biota's influenza drug Relenza).

In the drug development Game of Thrones, stick with the people who know what they're doing.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. As to whether or not he knows what he's doing, that's for others to judge