Biotech Daily

Friday May 23, 2025

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Amplia Therapeutics

By TIM BOREHAM

ASX code: ATX

Share price: 5.0 cents; **Shares on issue:** 387,952,669; **Market cap:** $19.4 million

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

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

Financials (March quarter 2025): receipts nil, cash outflows $2.73 million, cash balance $10.86 million, quarters of available funding 4.0

Identifiable major shareholders: Platinum Investment Management 10.4%, Acorn Capital 7.6%, Pengana Capital 3.9%, Blueflag Holdings 5.1%, Elk River Holdings (Chris Behrenbruch) 1.5%.

With some common types of cancers including breast and lung, therapies have developed at a rapid clip. The same can't be said for pancreatic cancer, which is not among the most common tumors but ranks number one as the deadliest.

Only 12 percent of patients will survive five years, compared to 21 percent for liver cancer and 23 percent for lung cancer.

Pancreatic cancer is hard to treat because it is diagnosed late and the tumors are hard to access. About 80 percent of tumors are found at the advanced stage.

In the barren drug development landscape, Amplia is making strides with its candidate that works on the anti-fibrotic path to tackling the disease.

Last week, Amplia shares surged up-to 76 percent after the company reported encouraging results from its key, ongoing phase Ib/IIa pancreatic cancer trial (see below).

Amplia CEO Dr Chris Burns notes some interesting emerging patient trends.

For unknown reasons, more under-50s are being diagnosed. The condition is rare in China, but increasingly common in South Korea. So, blame the ageing population, or the kimchi.

Dr Burns says pancreatic cancer is challenging to treat because of chemotherapy resistance caused by the presence of fibrous tissue that prevents the chemo from penetrating.

“There are a lot of different angles to it.”

Facts about FAKs

Amplia’s lead compound AMP945 (narmafotinib) is a focal adhesion kinase (FAK) inhibitor over-expressed in pancreatic cancer.

Most cancer treatments are designed to attack tumors directly by either poisoning them or starving them of nutrients.

AMP945 - discovered at the former Cancer Therapeutics Cooperative Research Centre - works by suppressing a bodily agent suspected of fostering the spread of tumors and fibrosis, removing the protective shields and rendering the tumors more responsive to chemotherapy.

True to the ‘cooperation’ angle, the effort involved scientists from Monash Institute of Pharmaceutical Services, the Peter MacCallum Cancer Centre, St Vincent’s Institute of Medical Research, the Walter and Eliza Hall Institute and the CSIRO.

Dr Burns says the science around pancreatic cancer and FAK is strong: patients with higher FAK do worse than those with lower FAK.

“We know FAK is involved in the fibrosis pathway.”

AMP-945 has US Food and Drug Administration fast-track and orphan drug designation.

Innate-ly interesting history

Amplia stems from Innate Immunotherapeutics, which failed miserably with a phase II multiple sclerosis (MS) trial.

Innate had a Trumpian angle, in that major shareholder Chris Collins was Donald Trump’s congressional liaison during Trump’s first spin in the White House.

Mr Collins was sentenced to 26 months' jail after pleading guilty to tipping-off his son that the MS trial was a dud, but Trump eventually pardoned him … of course.

Innate eventually acquired Amplia, owned by parties including Telix founder Dr Chris Behrenbruch and Dr Burns.

Amplia owns the FAK inhibitor program on which the company's trials are based.

"Chris Behrenbruch and I sat down and said why don't we start a company to actively develop the drug." Dr Burns said.

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

Done it before

Dr Burns has 30 years in drug discovery and development, including CEO positions at public and private companies. But his greatest claim to fame is co-developing the FDA-approved Ojjaara (momelotinib or CYT387), a so-called Janus kinase (JAK) inhibitor to treat myelofibrosis.

His co-inventor was Prof Andrew Wilks, who founded the formerly ASX-listed Cytopia and now runs the biotech funding vehicle Synthesis Bioventures. Both received the 2024 Prime Minister's Prize for Innovation.

To cut a long story short, Ojjaara eventually ended up in the hands of Glaxosmithkline in 2022, in a $US1.9 billion deal.

The FDA approved Ojjaara in 2023. This was a historical moment, given the agency had only approved two Australian-made drugs previously.

The others were Biota's influenza drug Relenza and – betcha didn't get this one - Hatchtech's Xeglyze for head lice.

On trial (1)

Dubbed 'Accent', Amplia's key trial is two-phase open-label combination study for first-line treatment of advanced metastatic or non-resectable (inoperable) pancreatic cancer.

Taking place at five local and two South Korean sites, Accent combines AMP945 with the standard-of-care generic chemotherapies gemcitabine and nab-paclitaxel (Abraxane).

Recruitment of the 55 patients has been ahead of schedule – a rare occurrence.

Last week, Amplia confirmed a ‘partial response’ in 15 patients, “a level of response sufficient to demonstrate that the combination of narmafotinib and chemotherapy is superior to chemotherapy alone”.

A partial response means a tumor has shrunk more than 30 percent, with the benefit sustained for two months or more.

The company says 15 of 50 patients would be enough to demonstrate efficacy “with reasonable confidence”.

The announcement followed a ‘poster’ presentation in late April to the American Association of Cancer Research’s annual shindig in Chicago, in which the company presented an analysis of the first 29 patients.

In short, AMP-945 was well tolerated, with “promising signs of activity substantially better than chemotherapy alone”.

The results?

Eleven patients (37.9 percent) had a partial response, compared with a separate study in which 98 of 431 patients (22.7%) on chemo alone had a partial response.

Twelve patients (41.4%) had ‘stable disease’, compared with 27 percent for chemo alone.

This amounted to an overall disease control rate of 79 percent (23 patients) compared with 50 percent for the chemo group alone.

Of the 21 patients showing reduced tumour size, 15 had a reduction of more than 30 percent.

Amplia expects to release top-line data from the fully recruited trial in around October this year.

Stop the growth

The trial has not resulted in any complete response – that is, the cancer disappears – but that’s not unusual for such virulent tumors.

“The most important thing with pancreatic cancer is not whether a tumor has shrunk 30 percent or 50 percent, but whether it has grown too much,” Dr Burns says. “If it grows too much, the patient is taken off the study. So, the amount of time on the study is a measure of how long [the drug is] keeping disease under control.”

To date, the duration has been almost double that for chemo alone: almost 200 days compared with 117 days.

“That’s what you care about as a patient: how long am I able to take these drugs to stop the disease progressing?” Dr Burns says.

On trial (2)

Amplia also has FDA approval for a secondary program that lines up AMP945 with Folfirinox, a combination treatment of four chemo drugs.

The open-label, single-arm, phase Ib/IIa trial will be in two parts, focusing on the “safety, tolerability, efficacy and pharmaco-kinetics of the combination in newly- diagnosed patients”.

Folfirinox is a cocktail of folinic acid (leucovorin), fluorouracil (5-FU), irinotecan and oxaliplatin and is the preferred pancreatic treatment in the US and most of Europe.

Folfirinox is fine in terms of efficacy, but toxicity is problematic.

In effect, AMP945 plus Folfirinox might offer the best of both words: longer survival with fewer side effects.

“Any time for these patients is precious, but you must play that off with the toxicity that goes with it, especially for older patients,” Dr Burns says.

Non-Amplia studies suggest progression-free survival of 6.4 months compared with around 5.5 months for gemcitabine/abraxane.

The overall survival benefit is more pronounced: 11.1 months, compared with about nine months.

In March, Amplia said it was in the final stages of planning the trial, having signed up contract research organizations and manufactured 30,000 capsules.

Enrolling up to 70 patients, the trial is expected to be carried out at five US sites and two local sites, with the first patient to be dosed by the middle of the year.

Finances and performance

Amplia reported a cash burn of $2.73 million in the March 2025 quarter, with available cash of $10.9 million.

The company’s coffers were refreshed in last year’s placement and rights offer that raised $13 million at 11.5 cents a share, a 15 percent discount to the prevailing price. Investors received options exercisable at 17.25 cents by October 2027.

The placement raised $7.8 million, with the rights raising pulling in $5.2 million.

In May 2024, Amplia raised $4.27 million in a rights offer at 5.5 cents a pop.

Amplia enjoys decent institutional support, with Platinum Investment Management, Pengana Capital and Acorn Capital all gracing the register.

Dr Behrenbruch resigned from Amplia's board in 2020 to focus on his Telix Pharmaceuticals, but he retains a 1.8 percent stake in Amplia.

Over the last 12 months, Amplia shares have dawdled between 17 cents (in mid-September last year) to the late April 2025 nadir of five cents (also the record low). They surged from 5.4 cents to 9.5 cents after last week's trial results, but didn't hold the gains.

In the post Innate era, the stock peaked at 27 cents in April 2021. In the Innate days, the stock got as high as $14, in January 2017 - allowing for a 10-to-one consolidation in 2018.

Sadly, no-one rang the bell to sell – except Chris Collins.

What else is out there?

Amplia is inspired by this month's FDA decision to grant accelerated approval for the Nasdaq-listed Varastem Inc's ovarian cancer treatment, based on a FAK inhibitor.

The combination treatment is for a narrow indication of low-grade serous ovarian cancer, following previous systemic therapy.

The approval was on the strength of a 57-patient trial that met its overall response rate with a 44 percent success rate – and despite 25 percent of patients having a long list of side effects.

As well as the usual nausea and diarrhoea, these included creatine phosphokinase, increased alanine aminotransferase, emesis, hyperbilirubinemia, hypertriglyceridemia, lymphocytopenia, dermatitis acneiform and thrombocytopenia.

Consult your nearest medical dictionary!

Dr Burns says if the drug is approved, it will clinically validate FAK inhibition across broader cancer treatments.

Amplia has done some preclinical work with ovarian cancer, but will seek collaborations to further the work. In other words: someone else needs to pay.

Dr Boreham's diagnosis:

In a familiar refrain heard across the biotech landscape, Dr Burns laments that investors don't appreciate Amplia's progress and are undervaluing the company.

But he argues that good science will prevail.

"We have had nothing but good news, including recruiting our trial two months ahead of schedule," Dr Burns says. "We have done a lot of good things, yet we don't get a lot of love from the market."

Dr Burns says Amplia has been built on the same strong scientific grounding behind Ojjaara.

“Many companies tried to make a JAK inhibitor and failed along the way,” he says.

“We stuck to exactly what we did. We did it well, tested it in every possible way and it always came out strongly.”

Of course, AMP945 is not about a pancreatic cancer cure, but buying more quality time for the patient.

“Commercially, while it is challenging you don’t have to do a lot for it to be meaningful,” Dr Burns says.

“If you can turn nine months survival into 15 months that means something to patients, and it means something to the market.”

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is surviving, overall and thanks for asking.