Biotech Daily

Friday May 23, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: EBR UP 8%; BOTANIX DOWN 5%**

*** DR BOREHAM'S CRUCIBLE: AMPLIA THERAPEUTICS**

*** BRANDON OPENS 2nd $5m DEMENTIA CUREATOR ROUND**

*** NEUROSCIENTIFIC: ISOPOGEN 1st STEMSMART CROHN'S PATIENT**

*** BOTANIX LOSES DIRECTOR MATTHEW CALLAHAN, 'MEDICAL ISSUE'**

*** OSTEOPORE STARTS CHILD TEMPORAL HOLLOWING IMPLANT TRIAL**

*** NYRADA RENAMES NYR-BI03 'XOLATRYP'**

*** PLATINUM REDUCES TO 10.6% OF SYNTARA**

*** NEUROSCIENTIFIC 4m BOARD OPTIONS, ISOPOGEN EGM**

*** ATOMO M-D JOHN KELLY APPOINTED INTERIM CHAIR**

MARKET REPORT

The Australian stock market was up 0.15 percent on Friday May 23, 2025, with the ASX200 up 12.2 points to 8,360.9 points.

Twenty-three of the Biotech Daily Top 40 companies were up, 12 fell, four traded unchanged and one was untraded.

EBR was the best, up nine cents or eight percent to $1.21, with 2.3 million shares traded.

Imugene climbed 6.25 percent; Resonance was up 5.3 percent; 4D Medical, Cyclopharm, Dimerix and Orthocell were up four percent or more; Curvebeam, Medadvisor and Starpharma improved more than three percent; Aroa, Cynata and Proteomics rose more than two percent; Compumedics, Medical Developments, Nanosonics, Prescient, SDI, Syntara and Telix were up one percent or more; with Clinuvel, Mesoblast, Neuren and Resmed up by less than one percent.

Botanix led the falls, down two cents or 5.3 percent to 35.5 cents, with 21.2 million shares traded. Optiscan and Universal Biosensors fell four percent or more; Atomo, Clarity and Paradigm lost more than three percent; Alcidion and Amplia shed two percent or more; Emvision and Micro-X were down more than one percent; with Avita, Cochlear, CSL, Polynovo and Pro Medicus down by less than one percent.

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 fostering 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 of Medical Research 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 and 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 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 presentation on the first 29 patients in April to the American Association of Cancer Research's annual meeting.

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

Subscribers also 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 most of 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.

Verastem won approval 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.

BRANDON CAPITAL

Brandon Capital says it has opened the second funding round for its Cureator Dementia and Cognitive Decline incubator program, with up-to $5 million for each project.

Brandon Capital said the program was a partnership with Australia's National Digital Health Initiative (AND Health) and Dementia Australia to address "two of the key barriers to commercialization and growth for digital health companies in Australia by providing access to both capital and digital health expertise".

Last year, the organization said it had opened the first funding round for applications for its up-to $5 million per project Cureator Dementia and Cognitive Decline incubator program, with non-dilutive funding from the Federal Government's Medical Research Future Fund to be "delivered in tranches upon reaching agreed milestones" (BD: May 23. 2024).

Today, Brandon Biocatalyst co-founder and chief executive officer Dr Chris Nave said that "in the fight against dementia, brilliant science alone won't win the battle, it takes vision, funding, and relentless execution".

"The Cureator program exists to fast-track Australia's world-class research into real- world solutions, because a day without progress is too many for the patients and caregivers impacted by dementia," Dr Nave said.

Applications close on July 10, 2025 and are available at: https://bit.ly/3yEaejs.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says Isopogen is preparing the first of up-to 12 special access program patients for Stemsmart mesenchymal stromal cells for fistulizing Crohn's disease.

Last month, Neuroscientific said it would issue scrip to acquire Perth's Isopogen WA and its Stemsmart cells for indications including Crohn's disease (BD: Apr 16, 2025).

Today, the company said the acquisition was subject to conditions, with the access program for fistulizing Crohn's disease to begin immediately following the acquisition.

Neuroscientific said fistulas were "one of the most severe and debilitating complications associated with Crohn's disease, are challenging to treat, and sustained healing has proven limited with standard therapies".

The company said Isopogen "confirmed that the first patient under the program has now commenced clinical preparation to receive their first of four weekly treatments", with treatment to begin about June 2, 2025 and evaluation to take between eight-to-10 weeks.

Neuroscientific said the program included an initial cohort of up-to four-patients followed by a second eight-patient cohort and if successful, it would progress to a phase I/II trial.

The company said the second cohort of patients would receive mesenchymal stromal cell therapy "as clinical products become available" from its manufacturers.

Neuroscientific was unchanged at 5.3 cents.

BOTANIX PHARMACEUTICALS

Botanix says "Matthew Callahan has stepped down as a director, effective immediately, to attend to a medical issue".

Botanix said the board thanked Mr Callahan for his "significant contributions to the company's evolution to date".

"Botanix is now a well-resourced, sustainable and rapidly growing commercial organization," the company said.

"We wish him a very speedy recovery, and both the board and Matt look forward to his return," Botanix said.

Botanix fell two cents or 5.3 percent to 35.5 cents with 21.2 million shares traded.

OSTEOPORE

Osteopore says it will conduct an up-to five-child study with Brisbane's Queensland Children's Hospital to treat temporal hollowing following cranial surgery.

Osteopore said the single-arm feasibility trial would assess its three-dimensional-printed, patient-specific poly-caprolactone-tricalcium phosphate 'onlay' scaffold combined with bone marrow aspirate and platelet-rich fibrin, to restore the fronto-temporal skull contour in children.

The company said temporal hollowing was a "noticeable depression in the lateral forehead and temple area" that occurred in up to 30-to-40 percent of patients following cranial vault remodelling, a "common surgical procedure" that aimed to correct cranio-synostosis abnormalities.

Osteopore said cranio-synostosis was a congenital condition in which the bones of a child's skull fused prematurely, potentially leading to abnormal head shape and neurological complications.

The company said materials like hydroxyapatite and porous polyethylene were used for augmentation but were only considered when the patient was reaching maturity, between 10-to-12 years old.

Osteopore said the procedure, with currently-used materials, required "a long, bi-coronal incision that stretched across the top of the skull from ear-to-ear".

The company said its scaffold had the potential to "support bone formation and growth as the child matures and may be implanted through a smaller incision".

Osteopore said the first patient had been recruited, with recruitment expected to be completed by 2027 and patient follow-up to continue for 12 months post-surgery.

The company said the study was supported by Plainland, Queensland's Maddox's Helping Hand Foundation, which helped clinicians access technologies that improve patient care.

Osteopore managing-director Dr Yujing Lim said "children don't have good options for bone or tissue implants".

"Most of what is currently available on the market is permanent and does not grow with the patient," Dr Lim said.

"It is important for us to collaborate closely with clinicians to identify key areas of development to drive impact and patient benefit," Dr Lim said.

Osteopore was unchanged at 1.4 cents with 2.2 million shares traded.

NYRADA

Nyrada says it will rename its lead drug candidate NYR-BI03 as 'Xolatryp' and has filed a trademark application for the name.

Nyrada said the name reflected the drug's "continued progress and demonstrated efficacy in models of ischemic stroke, traumatic brain injury and ischemia-reperfusion injury", but did not explain how 'Xolatryp' related to those indications.

Nyrada fell one cent or 6.9 percent to 13.5 cents with 1.35 million shares traded.

SYNTARA

Platinum Investment Management says it has reduced its substantial shareholding in Syntara from 190,988,001 shares (11.76%) to 172,160,847 shares (10.60%).

Sydney's Platinum said it sold shares between April 24 and May 21, 2025, with the single largest sale 6,372,040 shares on May 21 for $447,170, or 7.0 cents a share.

Syntara was up 0.1 cents or 1.5 percent to 6.7 cents with 2.7 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says its extraordinary general meeting will vote to issue its chair and three directors 1,000,000, each, exercisable at seven cents each within three years.
Neuroscientific said investors would vote to issue 1,000,000 options each to chair Chris Ntoumenopoulos and directors Tony Keating, Clarke Barlow and Anton Uvarov, in addition to their annual salaries.
The company said the meeting would vote to issue Perth's Isopogen WA 85,714,286 shares and 57,142,857 performance shares as consideration for its acquisition (see above).
Neuroscientific said shareholders would vote to approve the issue of shares and options under its placement, the issue of debt conversion shares and to establish a new class of share.
The meeting will be held at 216 St Georges Terrace, Perth on June 23, 2025 at 8.30am (AWST).

ATOMO DIAGNOSTICS

Atomo says it has appointed managing-director John Kelly as its interim chair, with "no changes to Mr Kelly's remuneration".
Atomo said the appointment followed "recent changes to the composition of the board and is considered appropriate at this time … to ensure continuity and stability in the leadership of the company during this period".
Last month, the company said it was restructuring its board for "cost savings" and had appointed Anthony May and Patrick Cook as directors, with chair John Keith and directors Deborah Neff and Dr Paul Kasian to resign (BD: Apr 24, 2025).
Today, Atomo said it intended to appoint a permanent chair "in due course".
Atomo fell 0.05 cents or three percent to 1.6 cents.