



Biotech Daily

Friday October 30, 2020

Daily news on ASX-listed biotechnology companies

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- * **QUEST TAKES 9% OF KAZIA; UNISUPER TAKES 6%**
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- * **REGAL FUNDS REDUCES TO 6% OF MEDADVISOR**
- * **JIMMY THOMAS, IVY PONNIAH REDUCE 0.07% TO 5% OF STEMCELL**

MARKET REPORT

The Australian stock market fell 0.55 percent on Friday October 30, 2020, with the ASX200 down 32.7 points to 5,927.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 20 fell, four traded unchanged and one was untraded.

Amplia was the best, up two cents or 10 percent to 22 cents, with 569,764 shares traded. Resmed rose 9.45 percent; Cynata climbed 8.6 percent; Cyclopharm was up 4.1 percent; Imugene, Oncosil and Prescient improved more than three percent; Dimerix, Immutep, Next Science and Orthocell rose two percent or more; Nova, Optiscan and Pharmaxis were up more than one percent; with Kazia and Starpharma up by less than one percent.

Osprey led the falls, down 0.2 cents or 9.1 percent to two cents, with 14.6 million shares traded. Antisense, Avita, Compumedics, Impedimed and LBT fell four percent or more; Alterity, Clinuvel, Genetic Signatures, Neuren, Polynovo and Volpara lost more than three percent; Cochlear, Mesoblast, Opthea and Uscom shed more than two percent; CSL, Medical Developments, Nanosonics, Pro Medicus and Proteomics were down more than one percent; with Paradigm down 0.4 percent.

DR BOREHAM'S CRUCIBLE: AMPLIA THERAPEUTICS

By TIM BOREHAM

ASX code: ATX

Share price: 22 cents

Market cap: \$23.6 million

Shares on issue: 107,441,000

Chief executive officer: Dr John Lambert

Board: Dr Warwick Tong (chairman), Dr Lambert, Dr Robert Peach, Dr Chris Burns

Financials (September quarter 2020): revenue nil, cash outflows \$523,000, cash balance \$3.76 million, quarters of available funding 7.2

Identifiable major shareholders: Platinum Asset Management 16%, Blueflag Holdings 7%, CTXT Pty Ltd (Cancer Therapeutic Cooperative Research Centre) 5.2%.

The notion that you can't teach old dog new tricks might have validity in canine husbandry, but it's less relevant in biotechnology circles in which companies constantly re-invent themselves.

In early 2018, Amplia was known as Innate Immunotherapeutics and it famously had just come a cropper with a phase II multiple sclerosis trial.

But not to worry. After considerable soul searching the company acquired the privately owned Amplia and its FAK inhibitor program. (Much more on FAKs later).

Innate changed its name to Amplia shortly thereafter (along with the board and most investors) and bunkered down to focus on treatments for pancreatic cancer and idiopathic pulmonary fibrosis (IPF).

Pancreatic cancer is one of the most fatal and difficult to treat cancers, while idiopathic pulmonary fibrosis is a debilitating lung disease

Amplia's (revamped) management diligently pursued its aims, while initially attracting little interest. But investors are now all-ears, with the stock quadrupling in value over the last 12 months.

Key catalysts are the start of a phase I trial and the US Food and Drug Administration's decision to bestow orphan drug designation for both conditions.

"The market took notice of these achievements which happened as and when we said they would," says chief executive John Lambert.

About Amplia

Amplia was owned by parties including biotech man-about-town Dr Chris Behrenbruch, scientist Dr Chris Burns and Peter MacCallum Cancer Centre researcher Dr Mark Devlin.

Amplia licensed the FAK assets from Cancer Research UK, with a patent life to 2033. But the program initially was the work of the Melbourne based, Federal Government-funded Cancer Therapeutics Cooperative Research Centre.

Dr Devlin is Amplia's chief scientific officer while Dr Burns graces the board.

The head of cancer drug and imaging outfit Telix Pharmaceuticals, Dr Behrenbruch resigned from Amplia's board in February this year to focus on Telix.

Dr Lambert joined Amplia as a consultant in August 2018 and became chief executive in June 2019, replacing Simon Wilkinson.

Previously, Dr Lambert worked at the not-for-profit enterprise Medicines Development for Global Health and before that he spent 14 years heading drug development at the 'flu drug house Biota.

Meanwhile, former Innate director and major shareholder Chris Collins has well and truly left the building. (But his wife Mary hasn't. Mr Collins transferred his remaining 3,329,570 shares to Mary a year ago when it was a 6.26 percent stake – since diluted to 3.1 percent.)

Mr Collins was Donald Trump's congressional liaison who held 17 percent of the old Innate and heavily spruiked the multiple sclerosis program in country club Republican circles.

In January Mr Collins was sentenced to 26 months' jail after pleading guilty to tipping-off his son about the failed trial. This month he reported into a Florida prison camp to begin his stir.

Making it, not FAKing it

Amplia's lead compound is called AMP945 which - speaking of name changes - could do with a new moniker given the woes of another AMP.

AMP945 is a focal adhesion kinase (FAK) inhibitor, which is all about suppressing a bodily agent suspected of aiding and abetting the spread of tumors and fostering fibrosis.

"Most cancer treatments are designed to attack tumors directly by either poisoning them, or starving them of nutrients," Dr Lambert says.

"This is fine when it works, but tumors are cunning in that they tend to mount a defensive response which blunts the effect of many cancer drugs."

Tumors indeed have sneaky ways of protecting themselves.

They spread cancer to other parts of body where secondary tumors take hold. They switch on new biologic pathways to compensate for the effect of the drugs. Or they physically shield the tumor and dampen the immune response.

“By inhibiting or suppressing FAK activity we hope to undermine the role FAK plays in these defence mechanisms,” Dr Lambert says. “The job [of AMP945] is to remove the shield so the cancer drugs can do the job they were designed to do.”

(En)roll up, roll up ...

The phase I trial is simple in nature, in that it intends to recruit 64 healthy volunteers at a single Australian site.

These kind folk will be subject to a single ascending dose, with later cohorts receiving multiple ascending doses.

The company expects recruitment to take six to nine months, with top-line results expected in mid-2021.

The trial is being undertaken by the Melbourne based contract research organization Nucleus Network.

If the results are positive, the company will lodge an investigation new drug application with the US Food and Drug Administration.

The oncology trials are likely to be in combination with an existing cancer drug, while the fibrosis treatment would be a monotherapy.

This (ad) alters nothing ...

Idiopathic pulmonary fibrosis (IPF) is a life threatening and progressive disease with limited treatment options. The median survival time is only two to three years if left untreated.

‘Idiopathic’ implies there is no known cause, but it is linked to risk factors such as smoking or workplace exposure to harmful particles.

The available drugs act on different targets and only slow progression rather than reverse the disease, while also having nasty side effects.

Students of Australian biotechs would be familiar with the story of Adalta, which is also focused on IPF. Unlike Amplia, Adalta is an immunological play based on tweaked antibodies called i-bodies. Amplia’s tech is based on shutting down a biochemical pathway that creates fibrotic tissues.

Sagely, Dr Lambert doesn't get roped into commenting on Adalta, except to note the companies are same but different.

Or as they (usually) say around Flemington on the first Tuesday in November: horses for courses.

Mandatory Covid-19 bit

As the world gets more insight into the workings of the Sars-Cov-2 virus, it's become evident the dreaded lurgy can result in longer term lung inflammation and damage.

Not surprisingly, this is "incredibly interesting" to Amplia - although to management's credit it's not flogging the potential.

Dr Lambert says: "This is of a great deal of interest to us; it appears the long-term complication of Covid-19 might be another source of lung fibrosis."

Amplia, by the way, is also interested in non-alcoholic steatohepatitis (NASH), the liver disorder caused by a build-up of fatty tissue. NASH is a bugger to treat and will be of enduring interest as capacious Asian nations such as China adopt poor Western diets.

Amplia's work is at an early stage but the company will build non-clinical data packages for other FAK inhibitor indications such as NASH and silicosis (a workplace conditions caused by exposure to particles).

"These are all important unmet needs and inhibiting FAK may play a role in treating each of these," he says. "We may initiate clinical studies subject to resources and commercial opportunities, but our focus more likely will be on licensing and co-development arrangements."

Amplia has another compound, AMP886, at pre-clinical stage for other fibrotic models.

"It has some interesting differences to AMP945 that might give utility in other therapeutic areas, such as ocular fibrosis," Dr Lambert says.

Finances and performance

Dr Lambert says Amplia is well placed to fund the phase I effort and the groundwork for a phase II trial, having raised \$4 million in a capital raising in August. Given this effort was at 10 cents, there have been smiles all around.

Earlier in the year, two institutions joined the Amplia register: Platinum Asset Management, which holds 16 percent and Blueflag Holdings with seven percent.

Amplia shares have gained 400 percent over the last 12 months, with liquidity increasing significantly as well.

On October 20, the company copped an ASX query when the shares surged from 29 cents to a record 35.5 cents, to which the company gave the Fawly Towers' Manuel response: "I know nothing".

The shares hit a record low of four cents on March 19 this year.

Dr Lambert says: "We have gone from a market capitalization of \$4 million 12 months ago, to around \$22 million today. Our liquidity has also increased significantly."

Dr Boreham's diagnosis:

On our usual cautionary note, Amplia is not the only drug developer interested in the FAK pathway and its clinical work remains at an early stage,

The Boston based Verastem is targeting a number of cancers by combining a FAK inhibitor with the so-called RAF/MEK pathways.

FAK! These acronyms are too much!

Based in Nanjing, China, Inxmed is combining a FAK inhibitor with an immune-oncology agent.

"The three of us are taking slightly different approaches to this," Dr Lambert says.

There's no doubt room for all, and in any event Amplia's focused approach on pancreatic cancer and IPF appears prudent: both conditions are prevalent enough to be meaningful, yet small enough not to attract the big development dollars.

While 30 percent of all new cancers are breast, lung or colorectal, pancreatic cancers account for a not insignificant 2.5 percent.

"It's a highly unmet need in cancer," Dr Lambert says. "Current immune-oncology therapies work well for lung cancer and many melanomas but have had virtually zero impact on pancreatic cancers."

While Collins and his Republican heavyweights might have been caught out with Amplia's former incarnation, our (legal) tip is that with a sub \$30 million market worth, the company is one to watch.

"It's a pretty exciting time for Amplia as we build momentum across multiple therapeutic opportunities and this provides attractive opportunities for investors," Dr Lambert says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He doesn't ride horses anymore because they are higher up than you think and very scary, a lot like the stock market.

[RESMED](#)

Resmed says revenue for the three months to September 30, 2019 was up 10.4 percent to \$US751,944,000 (\$A1,068,520,670) with net profit after tax up 36.9 percent to \$US185,374,000 (\$A263,450,770).

Resmed has previously said that it prefers to use the non-generally accepted accounting principles (non-GAAP) figure.

Resmed chief executive officer Mike Farrell said that “during the quarter, we continued to support the global Covid-19 pandemic response, providing ventilators, masks, and circuits to countries in need around the world”.

“In our core markets of sleep apnoea, [chronic obstructive pulmonary disease] and asthma, we are encouraged by the sequential improvement in new patient volume, as well as the ongoing strong adoption of our mask and accessories resupply programs,” Mr Farrell said.

“We have accelerated the launch of digital health [products] to help clinicians remotely diagnose, treat, and manage patients during the pandemic and beyond,” Mr Farrell said. Resmed said that non-GAAP diluted earnings per share was up 36.6 percent to \$1.27 a share and it had \$US421,414,000 in cash and equivalents at September 30 compared to \$463,156,000 at June 30, 2020.

The company said it would pay a dividend of 3.9 US cents (5.5 Australian cents) a share for the three months for the record date of November 11, on December 17, 2020.

Resmed was up \$2.41 or 9.45 percent to \$27.92 with 2.5 million shares traded.

[AUSBIOTECH, JOHNSON & JOHNSON INNOVATION](#)

Ausbiotech says the University of Queensland has won the 2020 Industry’s Choice Award, sponsored by Johnson & Johnson Innovation.

Ausbiotech said the University was involved in “dozens of global collaborations” in the fight against Covid-19 and had worked with Federal and Queensland governments, philanthropists and donors to develop a Covid-19 vaccine candidate.

The industry organization said that University of Queensland researchers “worked tirelessly to take the vaccine successfully through phase I trials and into CSL’s preparation for phase IIb/III trials planned for December 2020”.

“Research, clinical, and product development work that would normally take years has been accelerated into weeks and months, and planning that would typically take place sequentially is occurring simultaneously,” Ausbiotech said.

Ausbiotech said a collaboration with the Queensland University of Technology and the Walter and Eliza Hall Institute used a “first-in-Australia” approach to identify a genetic signature specific to patients with severe Covid-19.

[HYDRIX](#)

Hydrix said it has raised \$10 million in a placement to sophisticated and institutional investors at 28 cents a share, a 13.9 discount to the last closing price.

The company said the funds would be used to distribute and market devices including its Angel Medical Guardian implantable heart attack alert system and to repay debt.

Hydrix said Perennial Value Management and Regal Funds Management “corner-stoned” the raising and would become substantial shareholders.

The company said Bell Potter was lead manager to the placement with Henslow Pty Ltd co-manager and Holding Redlich the legal adviser.

Hydrix was up half a cent or 1.5 percent to 33 cents with 1.1 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has “taken back” the Australian distribution rights for its Pentrox inhaled methoxyflurane analgesic for pain relief from Mundipharma.

Last year, Medical Developments said it had appointed the Cambridge UK-based Mundipharma to distribute Pentrox in Australia (BD: Jun 3, 2019).

Today, the company said that since appointing Mundipharma as its distributor, the company had undertaken “a significant re-organization, causing both companies to review their arrangements on a market-by-market basis”.

Medical Developments acting chief executive officer Max Johnston said that “the separation of [Medical Developments] from Mundipharma is collegial and friendly”.

“We will resume servicing the business from December 1, 2020 and plan a smooth and orderly transition,” Mr Johnson said.

Medical Developments incoming chief executive officer Brent MacGregor said the company’s aim was “to take an urgent and much more direct and proactive role in the commercialization of Pentrox to capitalize on our global footprint of market authorizations”.

Medical Developments fell 10 cents or 1.85 percent to \$5.32.

OSTEOPORE

Osteopore says it has appointed LMT Surgical to market and distribute its regenerative bone technology in Australia and New Zealand for three years.

Osteopore said the Brisbane-based LMT Surgical would market Osteopore’s range of products for oculo-plastic and neurosurgical procedures, as well as patient specific implants.

The company said the distribution agreement was exclusive and did not contain binding minimum sales thresholds.

Osteopore was up one cent or 1.9 percent to 52.5 cents.

HYDRIX

Hydrix says will distribute Phyzhon Health’s Phyrari fractional flow reserve-wire cardiovascular sensor in Australia and New Zealand.

Hydrix said it had an exclusive four-year distribution deal with the Rancho Cordova, California-based Phyzhon, and would apply for Australian Therapeutic Goods Administration approval of Phyrari fractional flow reserve (FFR)-wire when the device was granted US Food and Drug Administration approval, expected by April 2021.

The company said the Phyrari FFR-wire was a disposable fibre optic pressure sensor guidewire used for interventional cardiology procedures.

Hydrix said the device used fibre optic technology to combine fractional flow reserve, used in angiogram procedures to measure blood pressure differences on either side of a coronary artery stenosis, and the ability to deliver a stent, allowing cardiologists to use it for diagnosis and stent implants.

The company said the Phyrari FFR-wire had a potential market demand of up to 125,000 units a year.

Hydrix general manager Paul Kelly said the Phyrari FFR-wire could “deliver immediate clinical benefits to patients and cardiologists and has the potential to reduce surgery times and costs as compared to current clinical products and procedures”.

IMMUTEP

Immutep says it has an agreement with Laboratory Corporation of America Holdings, or Labcorp, to develop immune-oncology products and diagnostics.

Immutep said that under the licencing and collaboration agreement, it was eligible to receive an upfront fee of \$US125,000 (\$A177,293) from the Burlington, North Carolina-based Labcorp, and up-to three milestone and service payments based on the commercialization of drugs resulting from the collaboration or new indications of existing drugs which use Labcorp's immune-oncology diagnostics.

Immutep was up half a cent or two percent to 26 cents with 1.9 million shares traded.

SIMAVITA

Simavita says it will seek shareholder approval to delist from the ASX and raise \$1 million to fund a capital reduction, partly due to the impact of Covid-19.

Simavita said it planned to continue as an unlisted company and commercialize its Smartz wearable and disposable nappy technology for adults and infants.

The company said it had been "significantly impacted by Covid-19" with the lockdown of the aged care industry in Europe and North America having reduced the company's capacity to complete essential clinical or market studies with key organizations.

Simavita said it would fund the capital reduction from its cash reserves and buy-back up to \$20,000 of Chess depository interests (CDIs) at 1.85 cents each from each shareholder at the record date of October 30, 2020, and the buy-back price was a five percent premium to the five-day volume weighted average price to October 30, 2020.

Simavita said that if the delisting were approved, shareholders who had not disposed of their holding would hold shares in an unlisted Canadian public company.

Simavita fell 0.3 cents or 15.8 percent to 1.6 cents with 4.8 million shares traded.

IMMURON

Immuron says its annual general meeting has passed all resolutions, but with up to 17.65 percent of votes against directors' shares and options.

Immuron said the largest percentage dissent was against 468,750 shares in lieu of cash to director Stephen Anastasiou, which had 5,319,125 votes (17.65%) opposed and 24,826,088 votes (82.35%) in favor.

The company said the issue of 468,750 shares in lieu of cash for directors Peter Anastasiou and Prof Ravi Savarirayan faced similar dissent, with 17.64 percent and 16.44 percent of votes against, respectively, while resolutions to issue 1.8 million options each to chair Dr Roger Aston and directors Daniel Pollock, Prof Savarirayan, Stephen Anastasiou and Peter Anastasiou had between 16.36 percent to 17.48 percent of votes against.

The company said resolutions to issue shares in lieu of fees to Dr Aston and Mr Pollock saw 16.37 percent and 16.52 percent dissent, respectively, with the opposition to Mr Pollock's shares attracting the largest number of opposing votes – 5,321,045 votes.

Immuron said the remuneration report passed with 87.96 percent in favor and the 50 percent director remuneration pool increase from \$500,000 to \$750,000 and the executive share option plan passed with similar margins, with the remaining resolutions, including the 10 percent placement facility and the re-election of Dr Aston passed by wider margins.

According to Immuron's most recent Appendix 2A, the 5,319,125 votes opposed to Stephen Anastasiou's shares amounted to 2.4 percent of the company, not sufficient to requisition extraordinary general meetings.

Immuron was unchanged at 25 cents.

AVITA THERAPEUTICS

Avita says it has adjourned its annual general meeting without any business being conducted due to insufficient attendance.

Avita said the minimum required attendance to hold the meeting was a simple majority, or 50 percent of shareholders and valid attendees of the meeting represented 49 percent of its shareholding.

Avita said the virtual meeting would resume on November 9, 2020 at 1pm (USWST) and November 10, 2020 at 7am (AEDT), and would be accessible at:

<http://www.meetingcenter.io/266106465>.

Avita fell 31 cents or five percent to \$5.93 with 820,294 shares traded.

MACH7 TECHNOLOGIES

Mach7 says shareholders will vote to issue 378,114 performance rights to managing-director Michael Lampron, and 63,300 shares and 85,000 options to directors.

Mach7 said Mr Lampron's proposed performance rights would vest based on the level of achieved total shareholder return, expiring on September 30, 2023.

The company said it proposed that the annual general meeting approve the issue of 30,480 shares and 35,000 options to chair David Chambers, and 21,100 shares and 25,000 options each to directors Dr Eliot Siegel and Robert Bazzani.

Mach7 said the shares were to be paid in lieu of cash for six months of directors' fees and the options would vest in three equal tranches over three years, expiring in five years and exercisable at the higher of the 30-day volume weighted average market price to the meeting, and the closing price on the date of issue, plus 10 percent.

The company said the meeting would vote adopt the remuneration report, re-elect directors Mr Bazzani and Dr Siegel, approve the company's long-term incentives plan and approve a 10 percent placement capacity.

The virtual meeting will be held on November 30, 2020 at 10am (AEDT) at:

<https://agmlive.link/M7T20>.

Mach7 was unchanged at 94 cents.

EXOPHARM

Exopharm says its annual general meeting will vote to issue 200,000 bonus shares to managing-director Dr Ian Dixon, based on undisclosed key performance indicators.

Exopharm said the proposed shares to Dr Dixon had been approved at the discretion of the board and would be issued within one month of shareholder approval.

The company said shareholders would vote to adopt the remuneration report, re-elect director Jason Watson and approve a 10 percent additional placement capacity.

The virtual meeting will be held on November 30, 2020 at 11am (AEDT), with registration at https://us02web.zoom.us/webinar/register/WN_D9NQW6MGQ6GoxEFJW1shBA.

Exopharm fell two cents or 5.2 percent to 36.5 cents.

TELEX PHARMACEUTICALS

Telex has requested a trading halt "pending an announcement regarding a proposed commercial transaction, which includes a material strategic investment".

Trading will resume on November 3, 2020, or on an earlier announcement.

Telex last traded at \$1.675.

KAZIA THERAPEUTICS

Sydney's Quest Asset Partners says it has increased its substantial shareholding in Kazia from 7,215,790 shares (6.27%) to 11,101,216 shares (8.80%).

Quest said that between October 10 and 27, 2020 it acquired 4,346,452 shares for \$3,477,929 or an average price of 80 cents a share and disposed of 461,026 shares for \$238,647 or an average price of 51.8 cents a share.

Earlier this month, Kazia said its institutional and retail rights offer at 80 cents a share raised a total of \$25.2 million (BD: Oct 2, 23, 2020).

Kazia was up half a cent or 0.6 percent to 79 cents.

KAZIA THERAPEUTICS

The Melbourne-based Unisuper says it has become a substantial shareholder in Kazia with 6,650,587 shares or 5.78 percent of the company.

Unisuper that between October 12 and 27, 2020 it purchased 6,650,587 shares off-market, but did not disclose the purchase price of the shares, as required under the Corporations Act 2001.

MICRO-X

Perennial Value Management says it has increased its substantial shareholding in Micro-X from 27,234,757 shares (7.63%) to 39,868,853 shares (11.16%).

The Sydney-based Perennial said that between October 12 and 28, 2020 it bought and sold shares, with the single largest purchase 9,412,098 shares for \$1,745,069 or 18.5 cents a share.

Micro-X was up half a cent or 2.8 percent to 18.5 cents.

MEDADVISOR

Regal Funds Management says it has reduced its substantial shareholding in Medadvisor from 17,835,705 shares (7.23%) 15,425,373 (6.22%).

The Sydney-based Regal Funds said that between May 28 and October 27, 2020 it bought and sold shares, with purchase prices ranging from 42 cents to 56 cents a share and sale prices ranging from 39 cents to 63 cents a share.

Medadvisor was up one cent or 2.6 percent to 40 cents.

STEMCELL UNITED

Jimmy Thomas and Ivy Ponniah say they have reduced their substantial holding in Stemcell United from 33,990,000 shares (5.30%) to 33,562,420 shares (5.23%).

The Melbourne-based Mr Thomas and Ms Ponniah said that between October 14 and 22, 2020 they sold shares for prices ranging from 2.2 cents to 2.41 cents a share and bought shares at prices ranging from 1.63 cents to 1.98 cents a share.

Stemcell United was up 0.1 cents or 6.7 percent to 1.6 cents.