Biotech Daily

Friday May 31, 2024

Daily news on ASX-listed biotechnology companies

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*** IDT REQUESTS 'CAPITAL RAISING' TRADING HALT**

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*** MELODIOL AGM 37% OPPOSE SHARES, 33% OPPOSE CONSOLIDATION**

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*** DR JEANNIE JOUGHIN REPLACES IMMURON'S DR ROGER ASTON**

MARKET REPORT

The Australian stock market rose 0.96 percent on Friday May 31, 2024, with the ASX200 up 73.5 points to 7,701.7 points. Twenty-three of the Biotech Daily Top 40 stocks were up, four fell, 12 traded unchanged and one was untraded. All three Big Caps were up.

Telix was the best, up $2.41 or 15.3 percent to $18.15, with 4.1 million shares traded. Avita and Percheron climbed more than 12 percent; Clarity and Dimerix were up more than eight percent; Atomo improved 7.1 percent; Clinuvel climbed five percent; Amplia, Cyclopharm, Cynata, Neuren and Next Science were up four percent or more; Alcidion, Nanosonics and Resonance rose more than three percent; Compumedics, Immutep, Nova Eye and Polynovo were up more than two percent; with 4D Medical, Cochlear, CSL, Emvision, Pro Medicus, Resmed and SDI up by less than one percent.

Opthea led the falls, down two cents or 3.8 percent to 51 cents, with 830,481 shares traded. Orthocell and Proteomics fell more than two percent; with Medical Developments down by 1.2 percent.

DR BOREHAM'S CRUCIBLE: AMPLIA THERAPEUTICS

By TIM BOREHAM

ASX code: ATX

Share price: 7.0 cents; **Shares on issue:** 271,609,233; **Market cap:** $19.0 million

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

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

Financials (March quarter 2024): receipts nil, cash outflows $554,000, cash balance 3.385 million*, quarters of available funding 2.5

Identifiable major shareholders: Platinum Investment Management 14.54%, Blueflag Holdings 6.94%, Pengana Capital 5.6%, Acorn Capital 5.19%.

In its pursuit of a cancer drug for pancreatic cancer and possibly other indications including ovarian cancer, Amplia has history on its side given the involvement of its leading figures in a US-approved drug for blood cancer.

The therapy in question, Ojjaara (momelotinib, previously CYT387) is a so-called janus kinase (JAK) inhibitor drug to treat myelofibrosis, developed by the formerly ASX-listed Cytopia. The lead inventors were Melbourne scientist and current Amplia CEO, Dr Chris Burns and Cytopia founder Prof Andrew Wilks.

In a typical case of ownership pass-the-parcel, Cytopia was sold to Canada's YM Biosciences for $14 million, CYT387 was acquired by Gilead for $US510 million ($A770 million) and then by Sierra Oncology (for a song). Glaxosmithkline then acquired the drug through its 2022 purchase of Sierra for $US1.9 billion - the highest amount ever paid for an Australian-developed therapy.

The US Food and Drug Administration (FDA) green-lighted the treatment last year, thus creating history, with the drug arguably only the third locally-invented drug to be approved by the agency (the others were Biota's flu drug Relenza and Hatchtech's Xeglyze for head lice and eggs); the legendary Gardasil is a vaccine.

"It was a very interesting time," Dr Burns says.

Can history repeat itself?

Amplia certainly can't be accused of targeting the low-hanging fruit, in that pancreatic and ovarian cancers are notoriously hard to detect and to treat. Amplia's lead compound, AMP945, targets fibrosis: the formation of excessive fibrous connective tissues that can impair the function of organs including the lungs, liver, heart and kidneys.

The company has orphan indication for both pancreatic cancer and idiopathic pulmonary fibrosis - another hard-to-treat condition.

Making Amplia Great Again

Amplia has an - er - interesting history.

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

There's even a Trumpian tinge to Amplia's history, in that former Innate director and major shareholder Chris Collins was Donald Trump's congressional liaison.

If Donald is convicted on his current charges, he knows who to consult about life in the clink: Mr Collins was sentenced to 26 months' jail after pleading guilty to tipping-off his son that the MS trial was less than tickety-boo. (Eventually, he was pardoned by Trump during his presidency).

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

Amplia was owned by parties including the now legendary Dr Chris Behrenbruch, Dr Chris Burns and Peter MacCallum Cancer Centre researcher Dr Mark Devlin (now an Amplia scientific adviser).

Initially, the program was the work of the Melbourne based, Federal Government-funded Cancer Therapeutics Cooperative Research Centre. While developed here, the rights resided with Cancer Research UK. But the organization wasn't actively developing it, so Doctors Burns and Behrenbruch negotiated to re-claim the tech.

Dr Burns took over from Dr John Lambert as CEO in December 2022. Dr John had replaced Simon Wilkinson in June 2019. Dr Burns has 30 years in drug discovery and development, including CEO positions at public and private companies.

Along the way, Dr Behrenbruch resigned from Amplia's board in 2020 to focus on Telix Pharmaceuticals - a sage decision given the radiotherapy outfit now has a $5 billion market value. He retains a significant shareholding. Innate changed its name to Amplia shortly thereafter and bunkered down to focus on its current programs.

What the heck is FAK all about?

Amplia's lead compound AMP945 (narmafotinib) is a focal adhesion kinase (FAK) inhibitor.

Most cancer treatments are designed to attack tumors directly by either poisoning them, or starving them of nutrients. 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.
It is hoped AMP945 will suppress a bodily agent suspected of aiding and abetting the spread of tumors and fostering fibrosis.

AMP945 removes the protective shields, rendering the tumors more responsive to chemotherapy.

AMP945 was discovered at the former Cancer Therapeutics Cooperative Research Centre, with the help of scientists from Monash Institute of Pharmaceutical Services and Peter MacCallum Cancer Centre, St Vincent's Institute of Medical Research, the Walter and Eliza Hall Institute of Medical Research and the CSIRO.

A great team effort all round, guys and gals!

On trial (and we're not talking about Trump)

Dubbed Accent, Amplia's trial efforts centre on a two-phase open-label combination trial for advanced metastatic or non-resectable (inoperable) pancreatic cancer.

A recently completed phase Ib dose-escalation study enrolling 14 patients dabbled with 100, 200 and 400 milligram deliveries and concluded that a 400mg dose was most suited for the phase IIa stage.

Combining AMP945 with standard-of-care generic gemcitabine and nab-paclitaxel (Abraxane), the phase Ib stage reported that six of the patients had a partial response, while the remaining eight patients had disease "stabilization" (they didn't get worse).

Seven of the 14 patients continued their treatment for more than six months, with two continuing after 10 months. This compares with the historic median progression-free survival of five and a half months for the standard-of-care therapy.

The phase IIa safety and efficacy effort will take place at six local sites and five in South Korea (a popular geography for trials given the in-situ skills and a compact population of 50 million).

The study aims for 26 patients initially, before interim analysis in six to seven months.

In a May 15, 2024 update, Amplia said the trial was going to plan, with 19 patients enrolled.

"An interim analysis will be conducted to determine whether six or more patients on the trial record a partial response," the company says.

If so, a further 24 patients will be enrolled taking the total to 50.

The most advanced patient to date has been treated for 300 days, with a best response of a 70 percent change from baseline.

The company expects to release interim data by September 30 this year.
Beyond that, the company has an open investigational new drug status with the FDA for a trial combining AMP945 with Folfirinox and is discussing potential funding with US pancreatic cancer charities.

Also known as Folfoxiri, Folfirinox is a combination treatment of four chemotherapy drugs (folinic acid, fluorouracil, irinotecan and oxaliplatin) and the preferred pancreatic cancer chemo in the US and most of Europe (but not in older patients because of toxicity issues).

Buying time

It should be stressed that with so many other cancer drugs, AMP945 is not pitched at a pancreatic cancer cure - it's all about buying more quality time for the patient.

In February, the FDA approved a Folfirinox variant called Nalirifox, a cocktail of four drugs for metastatic pancreatic cancer patients, who have not received previous treatment. Trials of Nalirifox showed an overall survival of 11.1 months, a statistically significant improvement over the 9.2-month overall survival with gemcitabine/Abraxane.

Based on its animal studies to date Amplia hopes it can do better - and with less toxicity than the standard of care, the generic gemcitabine and/or nab-paclitaxel (Abraxane)

"There's very clear evidence from the literature that inhibiting FAK synergizes with the activity of gemcitabine," he says. "We know if we put those together, we are supercharging gemcitabine activity."

He says pushing out the overall survival out from seven months to 12 months or beyond would be a "profound improvement" on the standard of care.

"If we could add four months or more that would be fantastic - patients could make it to their next Christmas, or their daughter's wedding."

Ovarian cancer

Because pap/cervical smears do not pick up the condition, around 70 percent of ovarian cancers are picked up in late stage and mortalities are high.

"As with pancreatic cancer, ovarian cancer is highly fibrotic, it's very difficult to treat and turns up quite late in testing," Dr Burns says.

In October 2023, Amplia presented pre-clinical ovarian cancer data to the American Association for Cancer Research special ovarian cancer pow-wow held in Boston.

The mouse model pertained to the highest grades of the disease, which account for 90 percent of all ovarian cancer patients. The data "clearly demonstrated" that narmafotinib improved tumor growth inhibition in chemotherapy-resistant ovarian cancer, relative to the standard-of-care, called niraparib.

The company is eying an investigator-initiated study, by which Amplia supplies the drug while another party funds the study and finds the patients.

Dr Burns is encouraged that the Boston-based Verastem Oncology is about to get accelerated FDA approval for a combo FAK drug for ovarian cancer (defactinib).

However, Verastem is targeting a low-grade ovarian cancer (which affects about 10 percent of patients), while Amplia focuses on the remaining high-grade patients.

Thus, the Verastem program validates the FAK approach whilst not being a competitor.

Finances and performance

On May 15, 2024, Amplia said it had raised $4.27 million in a rights offer, with most of the proceeds to be used to fund the Accent trial.

The two-for-five offer was struck at 5.5 cents per share. Investors put out their palms for $1.983 million, with most of the shortfall satisfied by underwriter Taylor Collison.

Director Dr Robert Peach also agreed to sub-underwrite up to $150,000 of shares and was allocated $105,000. Dr Burns and director Jane Bell cumulatively took up $78,000.

The raising takes the company's cash kitty to around $5 million, which Dr Burns says is adequate to fund the trial.

The stock is well-supported institutionally with Platinum Investment Management, Pengana Capital and Acorn Capital all gracing the register.

Over the last 12 months, Amplia shares have declined from 11 cents in May last year to 5.7 cents in mid-May, this year.

In the post-Innate era, the stock peaked at 80 cents, in March 2018.

Dr Boreham's diagnosis:

So far, the Federal Government's 'Made in Australia' push has centred on solar panels and critical minerals, but should it be extended to drugs as well?

"Despite years of government funding and academic work, not many drugs have got to phase III and only two have been approved," Dr Burns says.

"Others developed by Australian companies were bought in or were natural products."

If Dr Burns and Amplia have their way, a third drug (for pancreatic cancer) will be proudly bearing the made – or technically, discovered – in Australia logo.

"The difference with this [compared with the myelofibrosis] drug is I want to drive it locally for as long as we possibly can and see more of the success come back to Australia."

Patriotism aside, the unmet need is startling. In the US, 66,000 pancreatic cancer cases were diagnosed last year, with 50,000 deaths.

The current cost of treatment in the US alone is $US6 billion and is estimated to grow to $US36 billion by 2036.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. This column was proudly made in Australia.

TELIX PHARMACEUTICALS

Telix says data from 23 prostate cancer patients shows that TLX591 therapy led to a radiographic median progression-free survival of 8.8 months.

In 2022, Telix said it dosed the first of up-to 50 patients in the trial of TLX591 lutetium-177-labelled antibodies; and last year, said early data from 28 evaluable patients showed 18 had reduced prostate specific antigen (BD: Jan 27, 2022, Oct 19, 2023).

Today, the company said the study aimed to evaluate lesion concordance between gallium-68-based prostate specific membrane antigen-positron emission tomography (PSMA-PET) imaging and TLX591 dosimetry to validate PET imaging to select patients to receive therapy.

Telix said the study showed a median progression-free survival of 8.8 months "representing an encouraging signal of the potential efficacy of TLX591 in this patient population".

The company said the metastatic, castrate-resistant prostate cancer patients received two intravenous infusions of 76 millicuries (mCi) of TLX591, 14 days apart, with the majority of patients having undergone two prior lines of therapy.

Telix chief medical officer Dr David Cade said TLX591 was "a radio-[antibody drug conjugate] with significant potential advantages compared to small molecule radio-pharmaceuticals in treating prostate cancer".

"TLX591 is differentiated by a patient-friendly dosing regimen with far lower cumulative radiation exposure compared to small molecule radio-ligand therapies," Dr Cade said.

"This positive signal of efficacy … builds on prior studies that demonstrated the potential for TLX591 to deliver improved quality-of-life and durable tumor control in this advanced patient population," Dr Cade said.

Telix was up $2.41 or 15.3 percent to $18.15 with 4.1 million shares traded.

AVITA MEDICAL

Avita says the US Food and Drug Administration has approved Recell Go autologous cell harvesting device for thermal burn wounds and full-thickness skin defects.

Earlier this month, Avita said that it had responded to the FDA following its request for more data for the pre-market approval for the supplement of the spray-on skin Recell Go device (BD: Oct 2, 2023, Mar 1, 2024).

Today, the company said Recell Go streamlined the preparation of spray-on skin cells, reduced the training burden on medical staff, improved workflow efficiency and controlled "the Recell enzyme incubation time to ensure optimal cell yield and viability".

Avita said it would begin commercializing Recell Go in the US at burn treatment centres in June, with existing accounts to be "converted to Recell Go throughout the year".

The company said additional accounts would receive Recell Go with their first order, eliminating the need for conversion.

Avita chief executive officer Jim Corbett said that "FDA approval of Recell Go marks a paradigm shift in the treatment of partial-thickness and full-thickness wounds".

"By streamlining processes and enhancing operational efficiency with the use of Recell Go, clinicians can now treat a greater number of patients and more broadly experience the proven benefits of Recell technology," Mr Corbett said.

"We believe that this transformative shift will empower more clinicians to achieve optimal outcomes for their patients, driving greater adoption, and fundamentally redefining wound care management," Mr Corbett said.

Avita was up 33 cents or 12.4 percent to $2.99 with 1.9 million shares traded.

LITTLE GREEN PHARMA

Little Green says revenue for the year to March 31, 2024 was up 29.1 percent to $25,631,830, with net loss after tax up 55.2 percent to $7,279,313.
Little Green said sales of its medical marijuana flower products were up 71.6 percent to $15,761,723, with marijuana oil products down 16.7 percent to $8,651,358 and maiden $666,053 sales of vaporizer products.
The company said its increased loss was due to reduced exchange fluctuation on translation of foreign operations income from $4,515,026 in the previous corresponding period to $873,245 in the year to March 31, 2024.
Little Green said diluted loss per share was down 26.1 percent to 2.72 cents, with net tangible asset backing per share down 6.8 percent to 24.6 cents, and cash and equivalents of $4,973,504 at March 31, 2024 compared to $12,400,319 the prior year.
Little Green was up half a cent or four percent to 13 cents.

NOVA EYE MEDICAL

Nova Eye says five US Medicare Administrative Contractors (MACs) have proposed reimbursement changes excluding its minimally invasive glaucoma surgery (MIGS).
Last year, Nova Eye said proposed US Medicare local coverage determination changes for glaucoma surgery could “negatively impact” sales of its Itrack “in the short term” after five MACs had proposed to limit or deny coverage (BD: Oct 31, Nov 14, 2023).
In December, the company said all five MACs had cancelled the proposed changes, with US sales expected to be unaffected (BD: Jan 21, 2024).
Today, Nova Eye said the five Contractors had each published draft local coverage determinations that did not reimburse the use of stents in combination with a surgical minimally invasive glaucoma surgery “in the same patient eye, at the same time”.
The company said the determinations did “not make specific reference to the reimbursement coverage for [its] portfolio” including Itrack, Itrack Advance and Molteno3, “and hence reimbursement for surgeries with these devices remained unchanged”.
Nova Eye said the Contractors would provide a 45-day public comment period on the draft determination before determining whether to finalize, alter or scrap the changes.
The company said its Itrack and Itrack Advance devices were cleared by the US Food and Drug Administration for the catheterization and visco-dilation of Schlemm’s canal for the reduction of intraocular pressure in adult patients with open-angle glaucoma.
Nova Eye said the effectiveness of the Itrack and Itrack Advance devices “does not rely on the concurrent placement of a [minimally invasive glaucoma surgery] stent”.
Nova Eye was up half a cent or 2.1 percent to 24.5 cents with 1.1 million shares traded.

GENETIC SIGNATURES

Genetic Signatures has requested a trading halt pending “an announcement regarding a capital raising by way of an institutional placement and …. entitlement offer”.
Trading will resume on June 6, 2024, or on an earlier announcement.
Genetic Signatures last traded at 73 cents.

IDT AUSTRALIA

IDT has requested a trading halt in order to “finalize details of a proposed capital raising”.
Trading will resume on June 4, 2024, or on an earlier announcement.
IDT last traded at 10 cents.

BCAL DIAGNOSTICS

Bcal has requested a suspension, following Wednesday's trading halt "concerning a capital raising" (BD: May 29, 2024).
Trading will resume on June 3, 2024, or on an earlier announcement.
Bcal last traded at 17.5 cents.

MELODIOL GLOBAL HEALTH

Melodiol says its shareholders passed all 36 resolutions but with up-to 36.75 percent against shares for Brett Ayers and 32.85 percent against a second consolidation.
In February, Melodiol said it had completed a 20-to-one stock consolidation after an extraordinary general meeting voted 33.65 percent in opposition, and that it had 245,825,445 post-consolidation shares on issue (BD: Jan 23, 2024).
Earlier this month, the company said the annual general meeting would vote on a 30-to-one consolidation and to issue 41,500,161 shares, $12,195,220 in shares and 6,533,495 options to management and 16 companies, including $28,000 in scrip to Impactive managing-director Mr Ayers as consulting fees (BD: May 3, 2024).
Today, Melodiol said the Mr Ayer's shares were opposed by 56,998,448 votes (36.75%), with 98,115,711 votes (63.25%) in favor, and the consolidation had 50,899,159 votes (32.85%) against, with 104,063,095 votes (67.15%) in support.
The company said the meeting voted 22.09 percent against the remuneration report, with the 10 percent placement capacity and issue of shares to Harmonica Inc opposed by more than 23.12 percent of the vote.
Melodiol said apart from the issue of options to managing-director William Lay, which was opposed by 16.45 percent of votes, the remaining resolutions were passed more easily with between 9.74 percent and 13.54 percent dissent.
According to its most recent filing, Melodiol had 813,428,683 shares on issue, meaning that the 56,998,448 votes against Mr Ayer's shares amounted to about 7.0 percent of the company, sufficient to requisition extraordinary general meetings.
Melodiol was up 0.1 cents or 100 percent to 0.2 cents with 18.0 million shares traded.

AUSTCO HEALTHCARE

Austco's former executive chair Robert Grey says his 52,839,850 share-holding has been diluted from 17.73 percent to 14.65 percent.
Last week, Austco said it had raised $9.72 million at 18.5 cents a share, through a $6.9 million placement and a $2.82 million rights offer (BD: May 21, 2024).
Austco was unchanged at 18 cents.

ADALTA

Platinum Investment Management says its 87,863,759 substantial share-holding in Adalta has been diluted from 17.47 percent to 16.43 percent
The Sydney-based Platinum said that on December 19, 2023 it bought 7,500,000 shares for $150,000, or 2.0 cents a share, and between April 2 and 15, 2024 sold the 7,500,000 shares for $213,919, or 2.85 cents a share.
Last month, Adalta said it hoped to raise up-to $3,000,000 in a draw-down equity facility with New York's Bergen-managed New Life Sciences Capital LLC and up-to $700,000 from existing shareholder the Meurs Group (BD: Apr 29, 2024).
Adalta was unchanged at 2.5 cents.

PHARMAUST

Pharmaust says it has re-appointed managing-director Dr Michael Thurn on a $380,000 salary and appointed Dr Nicky Wallis as chief scientific officer, effective today.

Last year, Pharmaust said it had appointed Dr Thurn as chief executive officer on a base salary of $270,270 a year; and later, said it appointed John Clark as chief operating officer (BD: Aug 28, Dec 6, 2023).

Last month, the company said Mr Clark had been appointed interim chief executive officer after Dr Thurn resigned "for personal reasons and has given the company four months' notice as required under his contract" (BD: Apr 23, 2024).

Today, Pharmaust said Dr Thurn's "extensive experience and leadership in the pharmaceutical industry will be invaluable" as it begins its phase II/III study of monepantel for motor neuron disease, expected to begin enrolment before 2025.

The company said Mr Clark would step down from the board and re-commence his role as chief operating officer, effective from today.

Pharmaust said Dr Wallis had more than 12 years of experience in clinical and pre-clinical drug and device development and had worked for the Australian Clinical Trials Alliance, Lateral Pharma Biotech and Orygen Youth Mental Health Research.

According to her Linkedin profile, Dr Wallis held a Bachelor of Science and Doctor of Philosophy from the University of Melbourne.

Earlier this month, Pharmaust said chair Dr Roger Aston, directors Robert Bishop, Dr Thomas Duthy had resigned from the company, followed by the resignation of interim chair and 16-year director Sam Wright (BD: May 9, 17, 2024).

Pharmaust was up 2.5 cents or 13.5 percent to 21 cents with 4.9 million shares traded.

IMMURON

Immuron says it has appointed Dr Jeannie Joughin as a director, effective from June 1, replacing former chair Dr Roger Aston who has resigned, effective from today.

Immuron said Dr Aston had been a non-executive director since 2012 and was chair from 2012 until 2023 and had "decided now is a good time for him to resign as he resides in the UK and has family commitments there".

According to her Linkedin profile, Dr Joughin was a director at Bivacor, Immvirx, Hatchtech and CCRM Australia and had been a director at Glutagen and Paranta Biosciences; as well as Paradigm chief operating officer, Enable Injections chief commercial officer, marketing manager at Mayne Pharma and CSL Behring head of business development.

Dr Joughin's Linkedin page says she held a Bachelor of Science and Doctor of Philosophy from Melbourne's Monash University.

Immuron chair Paul Brennan said Dr Aston's contributions had "enabled Immuron to become a successful commercial entity with strong clinical programs underpinning our product differentiation".

Immuron fell 0.1 cents or 1.05 percent to 9.4 cents.