Biotech Daily

Friday June 24, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 24%; RESONANCE DOWN 11%**

*** DR BOREHAM'S CRUCIBLE: RECCE PHARMACEUTICALS**

*** HEXIMA FALLS 85% ON 'INCONCLUSIVE' PEZADEFTIDE NAIL FUNGUS TRIAL**

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*** DORSAVI, QBE EXTEND WORKPLACE SAFETY DEAL 3 YEARS**

*** CHIMERIC: FDA APPROVES CORE-NK CELL CANCER TRIAL**

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*** CEO STEPHEN TOMISICH DILUTED TO 51% IN TRAJAN**

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*** PERENNIAL REDUCES TO 12% OF LUMOS**

*** NAOS TAKES 31% OF BTC HEALTH**

*** SIMON GLOVER TO REPLACE 4D MEDICAL CFO HEALTH LEE**

MARKET REPORT

The Australian stock market was up 0.77 percent on Friday June 24, 2022, with the ASX200 up 50.3 points to 6,578.7 points. Thirty-two of the Biotech Daily Top 40 stocks were up, five fell, two traded unchanged and one was untraded.

Actinogen was the best on no news, up one cent or 24.4 percent to 5.1 cents, with 6.6 million shares traded. Prescient climbed 23.1 percent; Imugene improved 17.9 percent; Avita was up 16.15 percent; Micro-X rose 13.6 percent; Nanosonics and Paradigm were up 12 percent or more; Opthea and Telix were up more than 11 percent; Cyclopharm rose 10.9 percent; Universal Biosensors was up 9.4 percent; Clinuvel and Pro Medicus climbed eight percent or more; Amplia and Polynovo were up more than seven percent; Immutep and Next Science improved more than six percent; Atomo, Kazia, Mesoblast, Proteomics and Uscom were up more than five percent; Alcidion, Patrys and Starpharma climbed more than four percent; Antisense was up 3.7 percent; Neuren, Pharmaxis and Resmed rose more than two percent; with CSL, Emvision, Genetic Signatures, Impedimed and Volpara up by more than one percent.

Resonance led the falls, down 0.7 cents or 10.8 percent to 5.8 cents, with 863,646 shares traded. Compumedics lost 6.1 percent; Nova Eye fell five percent; Medical Developments shed 2.2 percent; Cynata was down 1.3 percent; with Cochlear down 0.2 percent.

DR BOREHAM'S CRUCIBLE: RECCE PHARMACEUTICALS

By TIM BOREHAM

ASX code: RCE

Share price: 76.5 cents; **Shares on issue:** 177,646,910; **Market cap:** $135.9 million

Chief executive officer: James Graham

Board: Dr John Prendergast (chair), Michele Dilizia, James Graham, Dr Justin Ward, Dr Alan Dunton (founder Dr Graham Melrose stepped down from the board in July 2020)

Financials (March 2022 quarter): revenue nil, operating cash burn $117,958, cash of $15.9m, quarters of available funding 135. Recce received a $3.08 million Federal Research and Development Tax Incentive during the period

Major identifiable holders: Dr Graham and Olga Melrose 21.6%, James Graham 3.4%, Michele Dilizia 1.9%, LDU Pty Ltd 1.7%.

Recce chief James Graham can speak from the heart about the dangers of sepsis, a life-threatening inflammation that spreads through the body via the blood as a result of infection.

Why? He was lucky not to die from the bacterial condition that kills about 20 percent of its 50 million sufferers.

After being attacked by a dog and clearly with an infection, Mr Graham hightailed it to hospital where they drew blood for a series of tests to match the bacteria with available antibiotics.

"It's clinical guesswork," he says. "They will go through a broad-spectrum cocktail of antibiotics, hoping that one works.

"Every hour they are left untreated, the patient's chances of survival decrease by eight percent."

As it happened, Mr Graham's staph infection was "fairly friendly" and easily treated.

But being a man of bioscience, he took along Recce's antibacterial drug candidate – Recce-327 (R327) - just in case.

Medical rules allow for experimental treatments when traditional first-line therapy has been exhausted and the patient is in imminent threat of expiring.

"I had an intravenous drip in one arm and a vial [of R327] in another," he says. "It was the back-up which fortunately we didn't have to use."

Germ warfare

An exponent of the broader problem of bacterial resistant to antibiotics, sepsis is caused by Staphylococcus aureus (Golden Staph) and Escherichia coli (E coli) but can also be caused by fungi and viruses.

Another sobering sepsis stat is that the condition is responsible for one in three hospital deaths - which merely confirms our suspicion that hospitals aren't healthy places.

"We are the only new class of antibiotic for sepsis at a clinical stage in the world," Mr Graham says, noting there hasn't been a new class of antibiotic for more than 30 years – primarily because the current ones are generic and cheap.

He says because there's no approved treatment, the clinical focus is on reducing inflammation (the result of the immune system hyper-reacting to the infection).

"Frankly, that's like putting the fire out in the back garden when the house behind you is burning down," Mr Graham says.

"You can have some benefit in reducing the inflammatory response, but if you are not tackling the underlying bacteria and infection spreading out of control, what's the point?"

Recc-on it will work?

Recce's phase I work centres on the synthetic broad-spectrum antibiotic candidate R327 and the variant for viral infections, R529.

Star Wars fans should not confuse these with R2D2.

The compound was discovered by Dr Graham Melrose, a biochemist who headed Johnson & Johnson's Australasian research arm for a decade.

He also headed the listed veterinary drug outfit Chemeq, which was a market darling before collapsing in 2007 after alleged breaches of continuous disclosure requirements. Dr Melrose had departed the company by then.

Dr Melrose's grandson, Mr Graham said his grandfather was motivated by the sudden death (from sepsis) of a football mate when he was in year nine. Not one for golf or carpentry, Dr Melrose's idea of a man cave was dabbling with test tubes in the garage and eventually the Eureka moment happened.

While the efforts were philanthropic at first, Dr Melrose and Mr Graham got together to commercialize the venture. Mr Graham has a degree in entrepreneurship.

"It was my pop and I coming together on a 'best endeavours' basis and we were the sole first investors. He is a real inspiration to us all," Mr Graham says of his grand-dad, now aged 89.

Recce was incorporated in 2007 and listed in January 2016, having raised $5 million at 20 cents apiece. It was co-founded by Dr Melrose's daughter Michele Dilizia, a medical scientist, former journalist and the company's chief scientific officer.

While Recce is headquartered in Sydney, Mr Graham recently moved to the US - sunny Florida in fact - to keep tabs on the company's operations there.

"We love what we do at Recce. It's about good people and great science," Mr Graham says.

Thank heaven for R327

Recce-327's mechanism of action involves hydrophonic interaction with the offending cells. The antibiotic travels through the blood and is attracted to a protein in the bacteria's outer membrane. This weakens the cell wall, causing the germs to burst (cell lysis).

The binding properties of R327 mean that it is more effective in tackling superbugs and it is effective on both Gram-negative and Gram-positive bacteria (the bugs fall into these two classes, as determined by the structure of the cell walls).

R327 is classed as a qualified infectious disease product (QIDP) by the US Food and Drug Administration, which means the regulator believes it can tackle "serious life-threatening infections caused by an anti-bacterial or anti-fungal resistant pathogen".

Interestingly, R327 is derived from common-as-muck ingredients polyethylene glycol, acrolein (a derivative of propene) and water (a.k.a. Adam's Ale or the elixir of life).

"Uniquely, it's a whole solution," Mr Graham says. "There is no singular active pharmaceutical ingredient; each and every part of the monomers in the polymers are working in unison as the active ingredient."

Meanwhile, R529 is 'same but different'. The manufacturing technique is similar, but the molecular structure and manufacturing steps are different enough to enable the compound to be patented. Both are made at the company's Macquarie Park facility in north-western Sydney.

Did someone mention Covid?

Given Recce's anti-viral ambitions, it should surprise no one that the company has been dabbling in a treatment for the dreaded and persistent severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) (the virus at the heart of Covid).

The plague unfolded shortly after Mr Graham was made CEO, which afforded him no period of grace before facing the usual lockdown operational dramas.

On the clinical side, the company noticed that the CSIRO and Doherty Institute were running a priority testing program of possible treatments, so the company entered what Mr Graham dubs this "school fete competition for little entrants to have a go".

“We made it through stage one with great success - 99.99 percent efficacy - and that moved us to stage two of a three-stage program.”

The next stage in the highly bureaucratic process is a bit vague, in that the company is “awaiting a mutually agreed outcome as to what may or may not happen next”.

One possibility is an all-in-one viral and bacterial prophylactic for sufferers of ‘long’ Covid.

Whatever the case, it’s very much a side program for Recce.

“Covid in my opinion will be with us for the time in hand and we have unique properties other compounds don’t,” Mr Graham says. “We are not there to participate in a ‘me too’ movement, but our compound appears to have good safety and efficacity on the virus side.”

Safety first

Recce has been doing a dose-escalation study to assess the safety of R327 in injected doses anywhere between 50 milligrams and 16,000 milligrams.

Enrolling 80 healthy volunteers, the study is being done locally but is also being shaped by feedback from the US Food and Drug Administration.

On Tuesday, the company reported the 10 male subjects in the 4,000 milligram cohort did not keel over, turn purple or froth at the mouth. In other words, the compound at that strength exhibited “good safety and tolerability”.

The final 16,000 milligram cohort is expected to be completed by June 30 (a.k.a. EOFY)

Mr Graham says while the study currently is indicated for sepsis, by phase II it could be expanded to other conditions such as kidney and urinary tract infections.

Wood-n’t it be good to tackle burns?

Alongside the dose escalation study, Recce has launched a Perth-based side program to show the efficacy of R327 as a spray-on topical treatment for burns infections.

This one is being overseen by prominent burns surgeon and Australian of the Year Prof Fiona Wood.

“Clinicians have reported a visible reduction in infection within the first 24 hours and a complete clinical response in all patients treated to date,” Mr Graham says.

He says the data will trickle out and should assuage the doubts of sceptics who think that R327 is no more than glorified infused water.

“We have something that has good safety and tolerability and meeting an unmet medical need.”

Finances and performance

As of the end of March 2022 Recce had a cash balance of $15 million, which provides a comfortable funding runway of 135.88 quarters (to be exact) on current cash burn rates.

The company raised $28.5 million in a placement in September 2020, at $1.30 apiece.

In 2018, Recce took out a $20 million at the market (ATM) facility via a local intermediary.

Popular in the US, ATMs are a flexible fundraising mechanism enabling companies to issue shares and raise capital at a time of their choosing, typically in smaller amounts.

Over the last 12 months Recce shares have gyrated between $1.35 (January 20, 2022) and 56 cents (last Monday). They spurted a lusty six cents (16 percent) on Tuesday, presumably on the back of the safety dosing news

Since listing they have traded as high as $1.64 (September 20, 2020) and as low as 15 cents (November 2016).

Recce shares have lost one third of their value over the last 12 months, but Mr Graham says that's not too bad relative to many of the company's peers.

Dr Boreham's diagnosis:

Mr Graham admits the dose escalation results are firmly in the 'boring but important' category.

But the burns side program promises some short-term sizzle - if that's not an inappropriate metaphor - for impatient investors.

"We don't do research for research's sake," he says. "We are working to a commercial outcome and that is to move the compound through the regulatory process as quickly as possible."

While Mr Graham is ensconced in Florida - amid a growing cohort of biotechs because of the tax breaks and other government assistance - the company will continue to be Australian based and ASX-listed.

"We are true blue as they come and unapologetic about it," he says.

"I may have personally moved to the US but at no stage have we ever considered turning our back on Australian shareholders or reducing our commitment to and investment in Australian activities."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is bugged by many things, but thankfully not sepsis, golden staph or E coli.

HEXIMA

Hexima says its phase II clinical study of pezadeftide for onychomycosis was "inconclusive … [and does] not support moving directly into a phase III program".
Hexima said the results "do not appear to correlate with results observed in its prior phase I study (HXP124-ONY-001) and do not support moving directly into a phase III program".
The company said it would "conduct a detailed review of the complete clinical trial data set and study conduct and expects to report its findings when complete".
Last year, Hexima said it had completed enrolment of 117 patients in its phase IIb trial of pezadeftide (HXP124) as a topical treatment for onychomycosis or nail fungus and the study was on-schedule to report results by July 2022 (BD: Jul 26, 2021).
In 2020, Hexima returned to the ASX following a $3.3 million initial public offer at 20 cents a share to fund its trial of HXP124 for onychomycosis (BD: Dec 4, 2020).
Previously, Hexima said it had it raised $40 million in an initial public offer to list on the ASX in 2007 and delisted in 2011 (BD: Nov 22, 2013).
In 2020, the company said it received $5.5 million through a private placement in September 2020 and would use the placement and initial public offer funds to complete a phase IIb trial of HXP124 for onychomycosis.
Hexima fell 22 cents or 84.6 percent to four cents with 21.6 million shares traded.

PAINCHEK

Painchek says it expects to raise $4.59 million through a $3 million placement and a $1.59 million, fully-underwritten, one-for-20 entitlement offer at 2.8 cents a share. Painchek said that the record date for the rights offer was June 29, with the offer opening on July 4 and closing on July 27, 2022.
The company said the capital would be used to fund regulatory proceedings with the US Food and Drug Administration, clinical trials, technology upgrades for its pain assessment applications, as well as sales, marketing, operations and support staff.
Painchek fell 0.1 cents or three percent to 3.2 cents with 4.5 million shares traded.

REDHILL BIOPHARMA

Redhill says revenue from Talicia, formerly Heliconda or RHB-105, for the three months to March 31, 2022, was up 12.8 percent on the preceding three months.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
In 2019, the company said the US Food and Drug Administration had approved the Talicia delayed-release capsules for Helicobacter pylori infection (BD: Nov 5, 2019)
Today, Redhill said it had an 80 percent increase in prescriptions for Talicia compared to the prior period "further cementing Talicia's position as the most prescribed branded [Helicobacter] pylori therapy in the US" but did not disclose the value of Talicia revenue.
The company said Talicia had been added to both California and Florida's Medicaid coverage, and "expects a major new coverage win to initiate July 1, 2022".
Redhill said its net revenue for the three months to March 31, 2022 fell 11.4 percent to $US18,236,000 ($A26,378,500) with net loss after tax down 25.0 percent to $US17,137,000 ($A26,788,800) compared to the previous corresponding period.
The company said it had $US28,847,000 in cash and equivalents at March 31, 2022 compared with $US75,972,000 at March 31, 2021
On the Nasdaq, Redhill was up 0.18 US cents or 0.23 percent to 76.84 US cents ($A1.11) with 55,729,892 shares traded.

DORSAVI

Dorsavi says it will provide its motion analysis technology to insurance company QBE Australia for a further three years following the 2020 agreement.

Dorsavi said that the previous agreement delivered about $180,000 to the company over the 16 months it was in effect.

The company said it would provide select QBE customers with its motion analysis technology to help reduce the risk of musculo-skeletal injuries and increase workplace safety, in turn reducing insurance claims.

Dorsavi chief executive officer Dr Andrew Ronchi said the company was “delighted to extend our strategic agreement with QBE and to continue providing its customers with access to our market leading sensor technologies”.

“The agreement has been a significant success for all stakeholders as we have helped improve the health and safety outcomes for customers,” Dr Ronchi said.

Dorsavi was up 0.1 cents or 10 percent to 1.1 cents.

CHIMERIC THERAPEUTICS

Chimeric says the US Food and Drug Administration has approved a 12-patient, phase Ib trial of its Core-NK cells in combination with interleukin-2 and vactosertib.

Chimeric said the investigator-initiated, safety and efficacy trial would be at the Cleveland, Ohio-based UH Seidman Cancer Center and would enrol patients with either locally advanced and metastatic colorectal cancers; or relapsed and refractory blood cancers.

The company said interleukin-2 was an approved therapeutic that was known to activate natural killer (NK) cells and that vactosertib was a clinical drug candidate that inhibited the transforming growth factor-beta (TGF-beta) signaling pathway “which has been shown to limit the effectiveness of immune therapies like NK cells”.

Chimeric said that UH Seidman oncologist Prof Eva Selfridge was an assistant professor at Ohio’s Case Western Reserve University School of Medicine and was leading the trial.

“Vactosertib has never been used in combination with NK cells in the clinic, but it has been used in humans in other clinical trials,” Prof Selfridge said.

“The goal of using it in this trial is to disrupt the TGF-beta signaling pathway that is so strong in colorectal cancer and cells,” Prof Selfridge said.

“We want to shut down that TGF-beta signaling pathway so that the NK cells can actually make it into the tumors,” Prof Selfridge said.

“Once they’re there, they have a chance of being active instead of just being silenced right away,” Prof Selfridge said.

Prof Selfridge said she was hopeful the trial would present patients “with more and better options for treatment and care”.

“T-cell-directed immunotherapy is only available for five percent or less of cancer patients, but immunotherapy is really the only way we have to cure people with metastatic disease,” Prof Selfridge said. “We’re just beginning our study, but ultimately the goal is to find immune therapies that work long-term.”

Chimeric chief executive officer Jennifer Chow said that “with the initial positive results seen in the phase Ia clinical trial with our Core NK platform cells, we have been eager to accelerate the development opportunities for it”.

“This study looks to combine novel therapeutics to overcome the challenges that are commonly thought to limit disease responses to NK cells,” Ms Chow said.

“We hope that this combination will allow us to see more complete responses in patients with difficult to treat diseases,” Ms Chow said.

Chimeric was up 0.6 cents or 6.9 percent to 9.3 cents with 1.6 million shares traded.

ORTHOCELL

Orthocell has requested a trading halt pending an announcement “in relation to a global exclusive licence and manufacturing agreement for its Striate+ product”.
Trading will resume on June 28, 2022, or on an earlier announcement.
Orthocell last traded at 30 cents.

POLYNOVO

First Sentier Investors Holding Pty Ltd says it has become a substantial shareholder in Polynovo with 33,266,983 shares or 5.03 percent.
The Sydney-based First Sentier said its ultimate parent company was Tokyo’s Mitsubishi UFJ Financial Group.
First Sentier said that it bought shares between March 10 and June 14, 2022, with the single largest purchase 1,532,490 shares for $2,061,681 or $1.345 a share.
Polynovo was up nine cents or 7.8 percent to $1.25 with 3.2 million shares traded.

TRAJAN

Trajan chief executive officer Stephen Tomisich and the Tomisich Family say their 76,470,588 share-holding has been diluted from 56.82 percent to 51.17 percent.
On Monday, Trajan said it had raised about $29.7 million in its fully underwritten institutional placement at $2.00 a share, and hoped to raise a further $5 million in a non-underwritten share plan at the same price (BD: Jun 20, 2022)
Trajan was up nine cents or 4.7 percent to $2.01 with 1.6 million shares traded.

UNIVERSAL BIOSENSORS

Richmond Hill Capital says it has become a substantial shar-holder in Universal Biosensors, with 10,685,532 shares or 5.04 percent of the company.
The Melbourne-based Richmond Hill said that between February 23, and June 23, 2022, it bought 3,697,600 Chess depositary interests for $1,986,072, or 53.7 cents an interest.
Universal Biosensors was up three cents or 9.4 percent to 35 cents.

LUMOS DIAGNOSTICS

Perennial Value Management says it has reduced its substantial in Lumos from 28,055,261 shares (14.56%) to 23,227,675 shares (12.06%).
The Sydney-based Perennial said on June 23, 2022, it sold 4,827,586 shares for $700,000, or 14.5 cents a share.
Lumos was unchanged at 12.5 cents.

BTC HEALTH

Naos Investment management says it has increased its substantial holding in BTC from 72,556,683 shares (29.48%) to 87,150,504 shares (30.92%).
The Sydney-based Naos said that on June 16, 2022, it bought 14,593,821 shares for $1,033,119, or 7.1 cents a share.
BTC Health was untraded at four cents.

4D MEDICAL

4D Medical says it has appointed Simon Glover chief financial officer to replace Heath Lee, effective from July 25, 2022.

4D said Mr Glover was most recently Medadvisor's chief financial officer and had previously worked for Coles, Tabcorp, Jetstar and KPMG.

4D was up 2.5 cents or seven percent to 38 cents with 1.5 million shares traded.