Biotech Daily

Friday August 6, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: NEUREN UP 10%; ACTINOGEN DOWN 11%**

*** DR BOREHAM'S CRUCIBLE: PATRYS**

*** PAUL HOPPER'S RADIOPHARM RAISING $65m FOR CANCER IPO**

*** RESMED REVENUE UP 8% TO $4.3b, PROFIT UP 13% TO $1b**

*** UNIVERSAL BIO H1 REVENUE UP 219% TO $3m, LOSS DOWN 29% TO $3m**

*** ANATARA 'SUCCESSFUL' BROMELAIN PIGLET STUDY NOT SIGNIFICANT**

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MARKET REPORT

The Australian stock market was up 0.36 percent on Friday August 6, 2021, with the ASX200 up 27.3 points to 7,538.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, 17 fell and seven traded unchanged. All three Big Caps were up.

Neuren was the best for the second day in a row, up 17 cents or 10 percent to $1.87, with 436,432 shares traded. Osprey climbed 7.7 percent; Cynata, Nova Eye and Optiscan improved more than four percent; Compumedics and Uscom were up more than three percent; Amplia, Kazia and Patrys rose more than two percent; CSL, Impedimed, Mesoblast and Volpara were up more than one percent; with Clinuvel, Cochlear, Pro Medicus, Resmed and Telix up by less than one percent.

Actinogen led the falls, down one cent or 10.75 percent to 8.3 cents, with 13.2 million shares traded. Impedimed fell four percent; Paradigm and Universal Biosensors lost three percent or more; Alterity, Dimerix and Next Science shed more than two percent; Cyclopharm, Genetic Signatures, Medical Developments, Oncosil, Orthocell, Proteomics, and Starpharma were down by more than one percent; with Avita, Nanosonics and Opthea down by less than one percent.

DR BOREHAM'S CRUCIBLE: PATRYS

By TIM BOREHAM

ASX code: PAB

Share price: 3.9 cents

Market cap: $70.96 million

Shares on issue: 1,819,596,905

Financials (June quarter 2021): revenue nil, cash burn $1.16 million, cash $10.91 million*****, quarters of available funding 9.39*

***** Includes $4 million in term deposits

Chief executive officer: Dr James Campbell

Board: John Read (chairman), Michael Stork (deputy chairman), Suzy Jones, Dr Campbell, Dr Pamela Klein

Identifiable major shareholders: Dr Dax Marcus Calder 10.2%, Stork Holdings (Michael Stork) 5.46%, Kemast Investments (Kerry M Stokes) 2.75%

The coronavirus pandemic continues to produce unexpected consequences - one of which is a shortage of monkeys.

We're not talking about the pesky rabies-ridden ones in Bali's Monkey Forest, but the two breeds of macaques - long-tailed and rhesus - favored by medical researchers for their physiological similarities with humans.

In the case of the rhesus monkeys, the US National Institutes of Health is investing $US29 million ($A40 million) in improving the facilities of the US National Primate Research Centres. China - the main breeding location for the long-tailed variety - has cut off supply to the West.

"The main problem is that demand exceeds supply," says Dr James Campbell, head of antibody drug developer Patrys.

"There has been so much demand from developers of Covid vaccines."

Dr Campbell says the Great Monkey Shortage is just one example of how the pandemic continues to present challenges for drug researchers.

The plague has also affected global supply lines and logistics - as evidenced by a glitch this week that knocked one-quarter from the company's valuation (see below).

About Patrys (no, not the orange juice brand)

Patrys is developing a cancer therapy to tackle some of the most difficult solid cancers, including glioblastoma (brain cancer), triple negative breast cancer and pancreatic cancer.

Patrys was formed in December 2006 to consolidate human antibody technology acquired from German parties, but that program is now kaput because of manufacturing issues that emerged. But not before the company raised funds for a phase II trial.

Dr Campbell took the reins in 2014 and licenced PAT-DX1 from Yale University in 2016.

The company's lead program, PAT-DX1, is about inhibiting DNA damage repair (DDR), which is normally a good thing but not when the mechanism allows cancer cells to survive.

PAT-DX1 is a humanized and smaller version of deoxymab 3E10 (D3E10), a DNA damage repair antibody first identified in the inflammatory immune disorder lupus.

While most antibodies bind to the surface of cells, deoxymabs like PAT-DX1 penetrate into cells, then cross into the nucleus where they bind to the DNA and kill DDR-deficit or mutant cells.

Dr Campbell likens the DDR systems to a road crew that repairs any 'potholes' in the cell's DNA sequence.

"If you have a DDR mutation, those holes aren't patched up and that's the basis of a range of cancers," he says.

In other words, the road crew is on a smoko.

Transcending the blood-brain-barrier

Glioblastomas are the most common type of high-grade primary brain tumor and the most dangerous. They grow quickly and have thread-like tendrils that extend into other parts of the brain, which makes surgical removal very tricky indeed.

The average survival time after diagnosis is 12 to 18 months, and only 25 percent of glioblastoma patients survive beyond a year.

As the body's most important organ - although some may disagree - the brain has extra protection from foreign objects.

Specifically, the brain's capillaries have fewer 'holes' than capillaries elsewhere in the body, allowing the delivery of only essential nutrients and hormones. The downside of this protection barrier is that it's hard to get many therapeutic drugs into the brain.

Dr Campbell reckons only 1.5 percent of small molecules can transcend the blood-brain-barrier (including the glioblastoma drug candidate being developed by ASX peer Kazia Therapeutics).

Two decades ago, this didn't matter so much, because treatment was all about surgery or radiation.

"There's a heap of really interesting cancer drugs that just can't get into the brain," Dr Campbell says. "We are in a strong position to go after cancers in the brain, whether they are primary or secondary cancers."

Indeed, Patrys has done quite a bit of pre-clinical work on treating brain metastases resulting from breast cancer.

"Outside of the potential in brain cancers we are also in a good position to go after other cancers with DNA damage repair mutations: triple negative breast cancers, pancreatic and colon cancer."

What's next?

Patrys is also broadening its portfolio with PAT-DX3, which is basically a full-sized version of the deoxymab antibody fragment PAT-DX1.

"As a larger molecule the mechanism of action is the same but the underlying pharmacology is different and PAT-DX3 stays in circulation longer than PAT-DX1," Dr Campbell says.

One idea for PAT-DX3 is deploying it as a vehicle to deliver other therapeutic 'payloads' (antibody drug conjugates, or ADCs).

Dr Campbell says antibody drug conjugates are particularly attractive in terms of delivering small molecules to a tumor site. "We have an antibody that we know is attracted to a range of tumors. So, what would happen if we could put a payload on it?"

Think of PAT-DX3 as the bodily equivalent of a Qantas Cargo 747 carrying a million doses of Pfizer.

PAT-DX3 can be used for ADCs because it has more conjugation sites (amino acids) than the smaller PAT-DX1.

"You could conjugate a traditional small molecule, or some peptides," Dr Campbell says. "We have a payload delivery system for an anti-cancer agent, but the delivery system also has anti-cancer properties so there's scope for really nice one-two punch."

In July 2021 the company said animal models suggested PAT-DX3 could also cross the blood-brain barrier.

"Prior to this data, it had not been established whether the larger size of PAT-DX3 would limit its ability to cross the blood-brain barrier," Dr Campbell says.

Patrys intends to follow this up with studies to compare the effects of both PAT-DX3 and PAT-DX1 on tumor reduction and survival in "range of primary and secondary brain cancer models."

Parp! Parp!

If PAT-DX1 is progressed, it needs to be better than a current suite of so-called PARP inhibitors, which also inhibit DNA repair.

(PARP stands for the enzyme poly ADP ribose polymerase, but we all knew that already.)

The leading PARP drug is Astrazeneca's lynparza olaparib, which is approved for a range of cancers. It is one of four approved PARP drugs that turn over $US2.3 billion a year.

"Generally, antibodies have fewer side effects than small molecules and we have the advantage that deoxymabs can transcend the blood-brain barrier," Dr Campbell says.

He says both PAT-DX1 and PAT-DX3 have potential as a "tumor agnostic" therapy.

The company has been doing some work with Sydney's Garvan Institute of Medical Research on pancreatic cancer, which is expected to be the second biggest fatal cancer by 2030.

(In the US there are about 60,000 cases a year).

Patrys is looking for local sites for a phase I trial, which will have a dose escalation component and will enrol solid cancer patients.

While doing the groundwork to get PAT-DX1 to clinic, the company is doing the drudge work of establishing stable cell lines, reproducing antibodies and getting toxicology down pat (excuse the pun).

This week the company reported a setback with this program, with its contract manufacturer unable to procure fermentation media equipment (no, not whisky stills) required for clinical-grade PAT-DX1 cell production.

As a result, the engineering run for PAT-DX1 is expected to be delayed until after September, with the tox studies rescheduled for the March quarter of next year.

These delays were attributed to the impact of the pandemic on global reagent production and are "outside the control of either Patrys or its contract manufacturer".

Imagion that

Meanwhile, Patrys has a collaboration with the ASX-listed, US-based Imagion, which is working on cancer imaging.

"We have a way of getting across the blood-brain barrier and they have a compelling cancer diagnostic technology, so it's a collaboration that could well deliver some interesting insights," Dr Campbell says.

Finances and performance

Patrys' June quarter update reveals just under $11 million of cash, following a placement and rights issue that garnered $7.3 million late last year.

In 2018, the company raised $7 million partly by way of a placement which included Perth billionaire Kerry Stokes.

In December 2018, Patrys received a $3 million insurance payout, pertaining to its abandoned legacy program.

Patrys listed in July 2007 after a $25 million raising at 40 cents apiece. Under Dr Campbell's watch, shares in the reinvented Patrys have grown from one cent, to as high as six cents in mid-July.

Last week's PAT-DX1 delay doesn't look like the end of the world to us, but it was enough to knock 26 percent off the share price over two trading sessions.

Stokes aside, Patrys is backed by Canadian tech investor Mike Stork (who's also on the board) and Perth periodontist Dr Dax Marcus Calder.

Dr Boreham's diagnosis:

Dr Campbell sees any decent biotech outfit as an "alignment of intellectual capital, human capital and financial capital".

Naturally, he believes Patrys has all three of these magic ingredients.

"We have a differentiated asset that localizes a range of tumors and penetrates the cells and locks the DNA," he says.

"Drug development is long and rigorous and hard. We are systematically de-risking assets and we have a path to the clinic."

Dr Campbell says DNA damage repair and blood-brain barrier therapeutics are high on big pharma's shopping list, as is anything that targets the most problematic cancers.

"We are ready to talk to people", he says, adding that 60 percent of cancer antibody deals are enacted before phase I stage.

He concedes that Patrys might lack razzmatazz, but he's unapologetic about the company's rigorous approach to science.

"I've been criticized for not being a showman," he says. "That's a criticism I'm happy to take, because frankly we're doing our job properly."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is surprised about the shortage of primates, given the degree of monkey-business surrounding last year's US election.

RADIOPHARM THERANOSTICS

Radiopharm Theranostics expects to raise $15 million in convertible notes ahead of a $50 million initial public offer to list on the ASX in November for cancer treatments.
Executive chair Paul Hopper told Biotech Daily that he combined technologies licenced from Imperial College London, New York's Sloan Kettering Memorial Hospital and the Technical University of Munich to form four separate platform technologies in radiopharmaceuticals for diagnosis and therapeutics.
Mr Hopper said that while he previously had focused on immune-therapies he had been aware of the radio-pharmaceuticals sector, which "was in the doldrums" in the US.
Mr Hopper said he changed his mind when Dr Christian Behrenbruch listed Telix Pharmaceuticals in 2017 and about the same time Novartis acquired two radio-pharmaceutical companies (BD: Nov 15, 2017).
He said that the four platforms were already in human clinical trials with three phase II trials and six phase I trials underway, with patients recruited.
Mr Hopper said that Weill-Cornell University's director of nuclear medicine Dr David Mozley had been appointed as the company's chief medical officer, with a chief executive officer to be announced soon.
Mr Hopper said that Bell Potter and Baker Young were the joint lead managers for the offer.
Radiopharm is a private company.

RESMED INC

Resmed says revenue for the 12 months to June 30, 2021, was up 8.1 percent to $US3,196,825,000 ($A4,327,693,310) with net profit after tax up 12.7 percent to $US780,621,000 ($A1,056,763,600).
Resmed said the revenue came from sales of its anti-snoring and sleep apnoea devices, as well as its ventilators, ventilation mask systems and remote ventilation monitoring and assistance software for Covid-19.
The company said it provided both US generally accepted accounting principles (GAAP) and non-GAAP data.
Resmed said it "uses non-GAAP information internally in planning, forecasting, and evaluating the results of operations in the current period and in comparing it to past periods ... [and] believes this information provides investors better insights". This report quotes the non-GAAP data.
Resmed said that cash and cash equivalents at June 30, 2021 was $US295,278,000 compared to $US463,156 ,000 at June 30, 2020,.
The company said that its non-GAAP diluted earnings per share was up 12.0 percent to $US5.33.
Resmed company said it would pay a dividend up 7.7 percent to 42 US cents a share for the three months to June 30, for the record date of August 19 and to be paid on September 23, 2021.
Resmed chief executive officer Mick Farrell said, "Our fourth quarter and full-year fiscal year 2021 results continue to demonstrate the strength and resiliency of our business".
"We faced some headwinds this quarter, as we annualized the $US125 million in Covid-related ventilator sales from this period in 2020 and we saw some tailwinds from a competitor's major quality issue that was announced during the quarter," Mr Farrell said.
Resmed was up nine cents or 0.24 percent to $37.27 with 1.4 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says that revenue for the six months to June 30, 2021, was up 218.95 percent to $3,391,888 with net loss after tax down 29.2 percent to $3,210,113.
Universal Biosensors said that revenue from sales of its Xprecia Stride coagulation analyzer test strips to Siemens was up 209.8 percent to $2,571,048, with initial sales from its wine testing devices.
The company said that revenue from services was up 251.4 percent to $820,840 compared to the previous corresponding period.
Universal Biosensors said its research and development spend was up 7.2 percent to $2815,850 for the six months to June 30, 2021, compared to the previous corresponding period.
The company said that diluted loss per share was down 50 percent to 0.2 cents compared to the previous period's 0.3 cents.
Universal Biosensors said that net tangible asset per security was down 20 percent to 12 cents a share.
Universal Biosensors said that it held cash and cash equivalents of $18,864,249 at June 30, 2021 compared to $32,146,365 at June 30, 2020.
Universal Biosensors fell three cents or 3.9 percent to 74 cents.

ANATARA LIFESCIENCES

Anatara says the "successful completion" of a piglet challenge study showed its bromelain formulation combination was better than standard feed, but not significantly so.
Antara said that piglets treated with its bromelain-based formulation (Boniff) and semi-moist extruded creep feed (Smec) were about six percent heavier than piglets on standard feed, while those on Smec alone were about 11 percent heavier ($p > 0.2$).
The company said that its pineapple-stem, bromelain-based Detach was a commercial product registered in Australia for the prevention of post-weaning diarrhoea.
Anatara said that Detach is a paste and required labor and effort to deliver the compound by drenching.
The company said that Boniff was a revised formulation applied to dry feed for piglets after weaning which reduced labor input and simplified the process.
Anatara said that given the experimental outcomes, Boniff could be considered a replacement for a non-physiological level of zinc oxide with commercial levels of additives in Smec.
The company said that pigs fed the Boniff-Smec diet performed equally, both with and without entero-toxigenic Escherichia coli inoculation, to pigs fed the Smec diet alone that comprised a pharmacological level of zinc oxide and levels of organic acids and phytogenics seen commercially, to assist in transitioning pigs in the post-weaning period.
"This suggests that at least under the conditions of this experiment, Boniff could be considered as a replacement for these additives," Anatara said.
Anatara chief executive officer Steve Lydeamore said the company was "pleased to have met its aim to develop alternative administration options and proof-of-concept in another species for its bromelain-based products".
"Anatara's animal health portfolio now includes Detach, ANR-pf for poultry and Boniff, an in-feed formulation for weaner piglets," Mr Lydeamore said.
"With this successful piglet study in hand, commercialization discussions will now commence with pig producers and animal feed [and] nutrition companies," Mr Lydeamore said.
Anatara fell one cent or 6.25 percent to 15 cents.

ANTEOTECH

Anteo says it has appointed UC Biosciences its Philippines Eugeni reader and severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid test distributor.
Anteo said the agreement with the Singapore-based UC Biosciences, also known as Unison, began on August 5, 2021, but did not say if there were minimum sales required.
Anteo chief executive officer Derek Thomson said the Philippines had a population of more than 100 million people and had “used rapid antigen testing as a tool within their pandemic response”.
“With Unison coming on board, we have expanded our distribution network and coverage across South East Asia,” Mr Thomson said.
Anteo was up 2.5 cents or 13.5 percent to 21 cents with 16.3 million shares traded.

IMUGENE

Imugene says that an extraordinary general meeting will vote on the issue of 119,354,838 consideration shares to Paul Hopper and other Vaxinia vendors.
Imugene said the resolutions proposed to issue 94,170,967 shares at 1.55 cents per share to Mr Hopper and 24,183,871 shares to unrelated Vaxinia vendors.
In 2019, the company said that through related company Vaxinia, it would acquire the exclusive license for the City of Hope-invented CF33 oncolytic virus technology to kill tumor cells and pay Vaxinia, whose major shareholder was Imugene executive chairman Mr Hopper, $462,500 in cash and $1,619,000 in shares, subject to conditions and shareholder approval (BD: Jul 15, 2019).
The company said that the on-line meeting will be held on September 7, 2021 at 9am (AEST).
Imugene was up half a cent or 1.75 percent to 29 cents with 18.9 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has appointed Dr Yi Lin as the first member of its “cellular immunotherapy scientific advisory board” (CI-SAB).
Chimeric said Dr Lin was currently a consultant at the Rochester, Minnesota-based Mayo Clinic’s division of haematology and experimental pathology.
The company said that Dr Lin was currently the Mayo Clinic Cancer Centre’s chair of the cellular therapeutics cross-disciplinary group.
Chimeric said that the cellular immunotherapy scientific board would work with its glioblastoma scientific advisory board.
Chimeric fell one cent or 2.9 percent to 33.5 cents.