Biotech Daily

Friday June 28, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.71 percent on Friday June 28, 2019, with the ASX200 down 47.5 points to 6,618.8 points.

Eighteen of the Biotech Daily Top 40 stocks were up, nine fell, nine traded unchanged and four were untraded.

Genetic Signatures was the best on no news, up 28.5 cents or 26.8 percent to $1.35, with 60,031 shares traded.

Imugene climbed 14.3 percent; both Oncosil and Telix improved six percent; Mesoblast and Paradigm were up more than four percent; Alterity, Avita, Benitec and Neuren were up more than three percent; Medical Developments, Pharmaxis and Volpara rose two percent or more; Cyclopharm, Opthea and Polynovo were up one percent or more; with Cochlear, Nanosonics, Pro Medicus and Resmed up by less than one percent.

Orthocell led the falls, down three cents or 5.6 percent to 51 cents, with 4.4 million shares traded.

Actinogen, Ellex and Impedimed fell more than four percent; Prescient and Starpharma shed more than two percent; Clinuvel, Cynata and Universal Biosensors were down more than one percent; with CSL down 0.1 percent.

DR BOREHAM'S CRUCIBLE: PATRYS

By TIM BOREHAM

ASX code: PAB

Share price: 2.5 cents

Market cap: $26.8 million

Shares on issue: 1,072,590,325

Financials (March quarter): revenue nil, cash burn $861,000, cash on hand $5.2million*****, estimated current quarter outflows $1.09 million

***** A further $2 million is in deposits with a maturity of more than three months

Chief executive officer: Dr James Campbell

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

Identifiable major shareholders: Dr Dax Marcus Calder 11.03%, Stork Holdings (Michael Stork) 9.23%, Mason Stevens 6.50%, Macquarie Group 6.21%, Kemast Investments (KM Stokes) 2.75%, Oncomab GmbH 2.05%, Marginata Pty Ltd (Roy Bolton Super Fund) 1.87%, Yale University 1.51%.

The cancer drug developer adheres to that perverse law of diminishing returns that states: "The more a biotech company progresses down its chosen therapeutic path, the less it should be valued."

In Patrys' case, the stock has lost almost half its value over the past year, despite the company's preclinical success with its quest to conquer the blood-brain-barrier that prevents effective drug delivery to the noggin.

"Today we have more than $7 million in the bank and we have shown our technology is robust," says CEO Dr James Campbell.

"I know the inherent value of the company is much higher."

One prominent Australian concurs: media and earthmoving equipment mogul Kerry Stokes holds a 2.75 percent Patrys stake, having participated in last year's placement.

A short history of Patrys

We suspect this fact isn't relevant, but Patrys means 'partridge' in Afrikaans and has nothing to do with a Greek island.

While Patrys initially was focused on gastric cancer, colon cancer metastases, and melanoma and multiple myeloma way back in 2008 to 2016, more recently its pre-clinical work has revolved around glioblastoma (brain cancer), triple negative breast cancer and brain metastases resulting from breast cancer.

The company's lead program, PAT-DX1 - acquired from Yale University in March 2016 - is about inhibiting DNA damage repair (DDR), which may sound like a good thing, but not if it is the cancer that is doing the repairing. PAT-DX1 is designed to enhance cancer death.

Discovered by Yale University boffins, 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, D3E10 nanoparticles penetrate them and transport the agent across the protective plasma membrane. Rather like Omo on those tough stains, it then binds to DNA and kills deficient or mutant cells.

Patrys was formed in December 2006 to consolidate human antibody technology from three sources: Germany's University of Wurzburg, the Teutonic biotech Oncomab and Acceptys Inc (a US company commercializing Columbia University know-how).

The company listed in July 2007, having raised $25 million at 40 cents apiece.

Patrys' original work related to immunoglobin-M antibodies, which are bigger and more complex than the immunoglobin B antibodies used in most therapies.

In 2013, the company raised funds for a phase II trial, but it was curtailed because of manufacturing issues.

About the study

The company's preclinical program relates to brain metastases stemming from triple negative breast cancer (TNBC), defined as tumors that don't express estrogen, progesterone, or the HER2 receptor.

These cancers account for 15 to 20 percent of breast cancers, with about 30 percent resulting in metastases (usually brain metastases).

"By the time they are diagnosed the patients normally have several of them and their life span is very limited," Dr Campbell says.

In December last year, the company announced the result of mice studies carried out by Yale Medical School, showing tumor reduction in 93 percent of the treated rodents. Also, 86 percent of the mice were still alive after the control ones had withered.

A follow-up effort, announced last month, compared PAT-DX1 with radiation therapy and in combination with the traditional treatment. Combined with lose dose radiation the compound “significantly increased” tumor suppression relative to both stand-alone PAT-DX1 and stand-alone radiation.

While last year’s study involved four weekly cycles of three doses per week, the latest one involved only one weekly cycle of three doses.

In other words, it worked just as effectively with a lower dose. “We wanted to prove an unequivocal crossing of the blood-brain barrier and we did just that,” Dr Campbell says.

What’s next?

Patrys and the Yale Medical School will “further explore the interaction between different radiation and PAT-DX1 dosing regimens that will inform and guide development [of the compound].”

Put another way, the next few months will be the boring-but-important phase of primate toxicity studies and formulation development, ahead of a phase I human study in late 2020 or early 2021.

“We are still doing pre-clinical work to inform what a study might look like,” Dr Campbell says.

In August last year, the esteemed Walter and Eliza Institute of Medical Research won a $100,000 Victorian government grant to combine PAT-DX1 with an antibody called 7D10 to produce - you guessed it - 7D10-PAT-DX1.

The idea here is that the 7D10 protein interacts with another protein called Bak to kill cells, but it can’t pierce the outer membrane to whomp the cancer cells. So like Omo Plus with active enzymes, combining the two might result in a more powerful treatment.

Finances and performance

Patrys is nicely cashed up, with $5.2 million of available moolah and $2 million in term deposits.

In February last year the company raised $2.4 million in an oversubscribed 2-for-11 rights issue at 1.7 cents apiece. Emboldened, management then followed up with a $4.6 million placement at 3.4 cents apiece, expanded from $3.5 million thanks to the patronage of Mr Stokes.

In December last year, Patrys then pocketed a $3 million insurance payout, relating to a botched manufacturing run pertaining to its old immunoglobin work. Dr Campbell says “we had to fight hard to get it”, which sounds very insurancey.

Since listing, Patrys shares have wavered between 32 cents in March 2008 and half a cent in August 2017.

As well as having Mr Stokes on the register, 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:

Delivering drugs across the blood-brain barrier has always been problematic, simply because the human body is constructed to keep the grey matter clear of foreign objects.

On industry estimates, the global market for TNBC drugs was worth $US296 million ($429 million) in 2015 and is forecast to rise to $US1.59 billion by 2025.

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

The difference is the PAT-DX1 antibody has fewer side effects and can transcend the blood-brain barrier.

The FDA approved the first PARP, Astrazeneca’s Lynparza in 2014.

(PARP, by the way, stands for the enzyme poly ADP (adenosine di-phosphate) ribose polymerase and you can thank Wikipedia for that one).

Dr Campbell says despite the perception that drug developers are only acquired at the later stage, big pharma has been known acquire pre-clinical antibody and biologics compounds.

In April 2018, Israel’s Compugen inked a circa $US200 million deal with Astrazeneca to develop genetically-engineered antibodies to treat cancer.

Around the same time, OSE Immunotherapeutics of France partnered with Boehringer Ingelheim to develop a checkpoint inhibitor to treat advanced solid tumors.

That deal reportedly was worth up to $US1.4 billion. But as is the norm, the drug has to work before the real spoils are delivered and that applies to Patrys as well.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is yet to transcend the blood-brain-barrier but certainly has cracked the other BBB – bulldust-baffles-brains.

VICTORIA GOVERNMENT

The Victoria Government says an Israel liaison officer will be based at Parkville's Melbourne Biomedical Precinct.

A media release from Victoria's Special Minister of State and Minister for Priority Precincts Gavin Jennings said that "as part of a new grant agreement with the University of Melbourne, the liaison officer will support research collaboration and commercialization opportunities within the Victorian and Israeli biomedical sectors".

The media release said that the Israel liaison officer would work on "opportunities across Victoria's entire biomedical sector, including other universities, research institutes and industry".

The Government said the University of Melbourne-based Israel liaison officer would support the work of the State Government's existing Tel Aviv-based biomedical director and would connect Israeli organisations with Victoria's biomedical sector.

The media release said that the officer would also collaborate with the Victorian Trade and Investment Office in Tel Aviv, established as part of the Victoria Israel Biomedical Innovation and Commercialization Exchange program announced in 2017.

The Government said the liaison officer would act as a conduit to Israeli, Australian and Victorian government funding opportunities to support research and co-operation, including the Victoria-Israel Science Innovation Technology Scheme.

The media release said that in 2016, there were 92 collaborations on biomedical publications between Israel and the Melbourne Biomedical Precinct partners.

The Government said it was working with the University of Melbourne to attract candidates for the appointment.

Mr Jennings said that the agreement would "further strengthen the work already being done at Parkville's Melbourne Biomedical Precinct, helping bring the world's best to Victoria".

RHINOMED

Rhinomed says it will support a Monash University study by Prof Darren Mansfield to explore the link between sleep and suicide.

Rhinomed said a 2016 study, titled 'Nocturnal Wakefulness as a Previously Unrecognised Risk Factor for Suicide', showed that wakefulness at night posed a greater risk for suicide than wakefulness at other times of the day.

The company said the study showed that when adjusting for the likelihood of wakefulness at a given time in 6-hour blocks, nocturnal suicides were 3.6 times more likely ($p < 0.001$).

The article was published in the Journal of Clinical Psychiatry and an abstract is available at: https://www.ncbi.nlm.nih.gov/pubmed/27337421.

The abstract concluded that "Being awake at night confers greater risk for suicide than being awake at other times of the day, suggesting that disturbances of sleep or circadian neurobiology may potentiate suicide risk."

Rhinomed, which is commercializing nasal dilators for sleep apnoea, said that Monash University would examine the National Coronial database for documentation on all Australian suicides in order to assess 10 years of 30,000 suicides, including demographic information, known health co-morbidities, timing and the mode of death.

The company said it would analyze wakefulness activities at the time of death as determined from the Australian Bureau of Statistics working times survey and adjust for the likelihood of wakefulness based on Australian community norms.

Rhinomed was up half a cent or 2.3 percent to 22.5 cents.

ANATARA LIFESCIENCES

Anatara says it is in discussions to manufacture its Detach non-antibiotic diarrhoea treatment for piglets, begin sales in Australia and expand into other markets.
Last year, Anatara said the Florham Park, New Jersey-based animal health company Zoetis Inc had exclusive rights to develop, manufacture, distribute and market Detach worldwide, including Australia, but earlier this month said Zoetis had terminated the licence (BD: May 15, 2018; Jun 14, 2019).
Today, Anatara said it was in discussions with an Australian Pesticides and Veterinary Medicines Authority-approved contract manufacturer for Detach in Australia.
The company said it was in discussions with Australian veterinary sales and distribution partners and was evaluating options for entry into Canada, South Korea and India, with China, the US and the EU requiring additional in-country field trials.
The company said it would develop its Detach treatment for other livestock animals, aquaculture and companion animals in each of the major markets and recently commenced a proof of concept aquaculture trial.
Anatara was up half a cent or 2.0 percent to 25.5 cents.

LIFESPOT HEALTH

Lifespot has requested a trading halt “pending an announcement in relation to a material product development and distribution heads of agreement”.
Trading will resume on July 2, 2019 or on an earlier announcement.
Lifespot last traded at eight cents.

AVITA MEDICAL

Blackcrane Capital says it has increased its holding in Avita from the equivalent of 145,186,212 shares (7.79%) to 164,724,549 shares (8.81%).
The Bellview, Washington-based Blackcrane said it bought 4,691,377 Australian shares and increased from 4,287,013 American depository receipts (ADRs), equivalent to 85,740,260 Australian shares, to 5,029,361 ADRs, equivalent to 100,587,220 shares.
The company said that it acquired the shares and ADRs between May 10 and June 27, 2019, with the single largest acquisition 261,916 ADRs equivalent to 5,238,320 shares for $US1,492,345 ($A2,142,595) or an average of 40.9 cents per share.
Avita was up 1.5 cents or 3.7 percent to 42 cents with 3.5 million shares traded.

BIONOMICS

Bionomics says it has further extended Dr Errol De Souza’s role as interim executive chairman to November 20, 2019.
In March, Bionomics said Dr De Souza would be paid $18,000 for 10 days a month, equivalent to $216,000 a year for 10 days a month for 12 months (BD: Mar 15, 2019).
On Wednesday, the company said that BNC210 had failed its second phase II trial, this time for agitation, following last year’s failure to meet the endpoints for post-traumatic stress disorder (BD: Oct 2, 2018; Jun 26, 2019)
Bionomics fell 0.2 cents or 5.9 percent to 3.2 cents with 17.3 million shares traded.