Biotech Daily

Friday April 20, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.21 percent on Friday April 20, 2018 with the ASX200 down 12.2 points to 5,868.8 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and three were untraded.

Psivida was the best, up 33 cents or 17.4 percent to $2.23 with 43,415 shares traded. Airxpanders climbed 11.5 percent; Genetic Signatures was up 10 percent; Actinogen rose 4.3 percent; Bionomics, Clinuvel and Starpharma were up more than three percent; Benitec and Osprey rose more than two percent; Avita, Compumedics, Nanosonics and Neuren were up more than one percent; with CSL, Resmed, Telix and Viralytics up by less than one percent.

Impedimed led the falls, down 5.5 cents or 7.6 percent to 67 cents with 2.1 million shares traded. Prana fell 4.4 percent; Cyclopharm, Mesoblast, Oncosil and Pharmaxis lost more than three percent; Admedus shed 2.9 percent; Polynovo, Pro Medicus and Volpara were down more than one percent; with Cochlear, Ellex, Opthea and Sirtex down by less than one percent.

DR BOREHAM'S CRUCIBLE: KAZIA THERAPEUTICS

By TIM BOREHAM

ASX code: KZA; **Nasdaq code:** KZIA

Share price: 69 cents; **Shares on issue:** 48,409,621; **Market cap:** $33.4 million

Chief executive officer: Dr James Garner

Board: Iain Ross (chairman), Bryce Carmine, Steven Coffey, Dr James Garner

Financials (December half): revenue $66,227 (down 54%), net profit $424,779 ***** (previous loss $4.182 million), cash $6.641 million (down 54%)

***** Profit reflects $7.98 million gain on legal settlement with Noxopharm, $165,000 by way of cash and the remainder by way of Noxopharm shares and options.

Major holders: HSBC Custody Nominees 36%******, Hishenk (Michael Abolakian) 11.2%, D&G Brown Investments 1.87%, Kilinwata Investments 1.83%, Dr Andrew Heaton 0.94%, El Coronado Holdings 0.94%

****** This holding consists of the Nasdaq American Depositary Receipts.

All diseases need a poster child to raise awareness - and research funding - and in the case of glioblastoma it's former US presidential Republican candidate and war hero John McCain.

In a bipartisan vein, the common and aggressive form of brain cancer also killed Ted Kennedy and Beau Biden, son of former Democrat Veep Joe Biden.

They're not alone.

In the US, 12,500 new patients are diagnosed annually and about 1,600 here. Untreated, sufferers have an average four-month life expectancy, rising to 12 to 15 months with treatment.

The good news is that there is an existing standard of care drug, called temozolomide. Or at least good news for some because the drug (administered after surgery or radiotherapy) is effective in only one-third of cases.

When Crucible was at school that was a big fat fail. Now, of course, it's a participation certificate.

Formerly Novogen, Kazia is taking a new approach with a brain cancer therapeutic called GDC-0084, which Novogen bought from Glioblast Pty Ltd in October 2016.

But Glioblast licenced the compound from Roche's Genentech. And who is Glioblast? I'm glad you asked. In the very small biotech world, the Sydney company was owned by Viralytics chairman Paul Hopper and Genentech's former program leader for GDC-0084, Leslie Chong, now Imugene's chief executive officer.

Enough history

The molecule inhibits a signalling pathway called P13K, which is expressed in 85 percent to 90 percent of glioblastoma tumours.

Kazia chief Dr James Garner says there's been little progress in treating brain cancers for the last 15 to 20 years. One reason is that other drugs (such as for breast and lung cancer) have been re-purposed for glioblastoma.

"GDC-0084 was designed specifically as a treatment for brain cancer so it has been carefully optimised in the disease area," Dr Garner says.

Silver medal for longevity

Kazia is based on the shell of Novogen, the second oldest ASX-listed biotech (Circadian, now Opthea, takes out the gold medal).

Also Nasdaq listed, Novogen changed its name to Kazia in November last year, which could mean "cinnamon tree" in Hebrew or "commands peace" in Polish, but the company was simply looking for a name that wasn't Novogen and settled for one that sounded like a 1980s keyboard.

Founded by Dr Graham Kelly, Novogen listed on the ASX in 1994 and then on the Nasdaq in 1998. In its tortured history Novogen had many guises, including a developer of veterinary products and women's natural health supplements, not to mention red clover leaf derivatives for cancer.

Dr Kelly left the company in 2005 after a strategic difference of opinion with the board, only to return as CEO in 2012.

During his absence, Dr Kelly was a regular critic of Novogen on his personal website - which made for interesting reading to say the least. He departed (again) in 2015 to found Noxopharm.

Novogen's board recruited Dr Garner in 2016 to take the company along a more commercially-focused path, rather than dabbling in early stage stuff that never went anywhere.

Novogen then engaged in a legal spat with Noxopharm over intellectual property.

In a settlement late last year, Novogen/Kazia agreed to renounce any rights to Noxopharm's intellectual property, in return for Noxopharm stock and options worth $7.81m and $165,000 of cash.

Kazia retains a second program for ovarian cancer, Cantrixil, a third generation benzopyran molecule that has shown activity against cancer stem cells. Other preclinical assets were hived off to Heaton-Brown Life Sciences, founded by former Novogen CEO Dr Andrew Heaton and erstwhile chief scientific officer Dr David Brown.

Kazia retains 10 percent equity in Heaton-Brown, plus milestone payment entitlements.

What Kazia does

The GDC-0084 licencing deal involved Novogen buying the program for $US5 million up front, plus royalties in line with industry standards and a performance payment component "linked to regulatory and commercial outcomes."

"The Genentech transaction bought a technology more recognizable to clinicians and investors," Dr Garner says. "It was something easier to talk about."

So if the prospects were so good, why did Genentech give it up?

"Genentech produces more drugs than they have the resources to take forward," he says. "It's not uncommon for a drug to go [to] three or four owners before it becomes a product."

GDC-0084 tackles glioblastoma multiforme, which sounds like a vitamin tablet but is the most common form of glioblastoma accounting for 15 percent of all brain cancers.

Kazia last month won 'orphan drug' status from the US Food and Drug Administration.

A 47-patient, phase I trial run by Genentech showed safety and some signs of efficacy and Kazia is now recruiting for a 228-patient phase II trial, initially at the University of Oklahoma's Stephenson Cancer Centre but then at other US centres.

While most clinical trials enrol difficult-to-treat patients that have failed other treatments, this trial gives the opportunity to target a first-line therapy compared with the (ineffective) temozolomide.

The chosen primary endpoint of progression-free survival rather than overall survival should enable quicker data readouts, with Kazia targeting full recruitment in 12 to 18 months, and first data 12 months thereafter.

Dr Garner says the trial has been designed in view of accelerated approval, "but there are no guarantees".

Prospects and financials

While a rare cancer, glioblastoma was a $US1 billion a year market for Merck before its temozolomide drug Temodar went off-patent.

Dr Garner notes that three drugs support a form of lung cancer suffered by only two per cent of lung cancer patients.

“Increasingly we are seeing cancer as a group of many smaller diseases,” he says.

Novogen shares have traded as high as $13.70 (in May 2008) and as low as 33 cents (in December last year). In its Kazia reincarnation the stock has more than doubled.

Including cash, receivables and pending Federal Research and Development Tax Incentives, the company has $14.8 million of current assets - enough to fund the trial and other costs until the end of 2019.

“But we will need some additional funding to see us through to completion of the study,” Dr Garner says.

Flattering comparisons

Globally, other biotechs in the P13K field are attracting juicy valuations.

The Nasdaq listed, phase I Infinity Pharmaceuticals is valued at $US130 million. TG Therapeutics, which also graces the Nasdaq and is in phase II/III stage, is worth a cool $US1.2 billion.

Locally, Kazia shares DNA with the preclinical stage Patrys (ASX code: PAB), which is also targeting glioblastomas.

Attentive readers will know we covered the stock a couple of weeks back.

Dr Boreham’s diagnosis:

Currently, two P13K inhibitors have been approved for blood cancers: Bayer’s Aliqopa (copanlisib) and Gilead’s Zydelig (idelalisib).

So the science is accepted, generally speaking.

Kazia doesn’t look like the sort of play for short-term investors, given we’ll have to wait some time for the GDC-0084 clinical results.

However initial data from the phase I Cantrixil program is expected in the current quarter.

With a compact $35 million market cap backed by $6 million of cash Kazia, like peace, deserves a chance.

As chairman Iain Ross told the company’s AGM last year: “We feel that (the company) deserves to be judged on its own merits and not on the strengths of weaknesses of the distant past”.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he has won many participation certificates.

RESMED

Resmed says it has an amended and restated $US800 million ($A1,037.4 million) credit agreement with MUFG Union Bank NA and Westpac Banking Corporation.

In an US Securities and Exchange Commission filing, Resmed said that the New York-based Mitsubishi UFG Union Ban would be the administrative agent, joint lead arranger, joint book runner, swing line lender and letter of credit issuer, with Australia's Westpac as syndication agent, joint lead arranger and joint book runner.

The company said that the agreement, provided "a senior unsecured revolving credit facility in an aggregate amount of $US800 million, with an uncommitted option to increase the revolving credit facility by an additional $US300 million.

Resmed said the agreement amended and restated an October 31, 2013 agreement with MUFG, HSBC Bank USA, National Association which provided a $US1.3 billion senior unsecured revolving credit facility.

The company said that the agreement would terminate on April 17, 2023, when all unpaid principal and interest under the loans must be repaid.

Resmed said the facility would bear interest at a rate equal to the London inter-bank offered rate (Libor) plus 0.75 percent to 1.50 percent, depending on the then-applicable leverage ratio, or the base rate as defined in the facility plus 0.0 percent to 0.50 percent depending on the then applicable leverage ratio, with an applicable commitment fee of 0.100 percent to 0.175 percent depending on the then-applicable leverage ratio on the unused portion of the facility.

The company said the funds would be used for general corporate purposes.

In 2011, Resmed signed an up to $US400 million credit agreement at 1.5 to 2.0 percent above the Libor rate (BD: Feb 16, 2011).

In 2013, the company entered into a $US1.0 billion facility with an interest rate of Libor plus 1.0 percent to 2.0 percent (BD Nov 6, 2013).

Resmed was up three cents or 0.2 percent to $12.95 with 3.3 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has Conformité Européenne (CE) mark approval for its Easyscreen kit for hospital acquired and antibiotic resistant pathogens detection.

Genetic Signatures said its second CE mark approval allowed the marketing in Europe of the Easyscreen extended spectrum beta-lactamase and carbapenemase producing organisms (Easyscreen ESBL & CPO) detection kit.

The company said that the kit detected hospital superbugs or antibiotic resistant pathogens which were a significant global concern as standard treatments might be rendered ineffective.

Genetic Signatures said that the Easyscreen ESBL & CPO kit allowed for rapid detection in less than three hours with minimal hands-on time for laboratory technicians.

The company said the kit was designed to provide rapid and accurate detection of 16 beta-lactam and carbapenem-resistant pathogen targets and it would be sold in Europe through a hybrid of direct and distributor-led sales, with recruitment underway to build a direct sales team in Europe.

Genetic Signatures chief executive officer Dr John Melki said the company was "very excited to receive a major international approval for our Easyscreen technology".

"This registration follows significant work from the Genetic Signatures team and ultimately reflects the significant potential of our three-base technology to make a real difference in pathogen detection and treatment processes," Dr Melki said.

Genetic Signatures was up 2.5 cents or 10 percent to 27.5 cents.

CYNATA THERAPEUTICS

Cynata says its licence with Apceth has been terminated and it has filed an Australian patent application to cover its Cymerus technology for Car-T therapy side effects.

Last year, Cynata said the Munich, Germany-based Apceth GmbH & Co had dropped cancer indications but retained an option on its Cymerus mesenchymal stem cells for other indications (BD: Mar 31, 2017).

Cynata said at that time that Cymerus cells "demonstrated characteristics appropriate for Apceth's technology, an outcome both parties considered successful".

In 2016, Cynata said it had a licence option agreement with the Apceth to use its stem cell technology with genetic modification for new indications including cancer and the agreement included an undisclosed up-front payment and milestones, worth potentially more than $40 million as well as royalties on sales (BD: May 9, 2016).

Today, the company said its licence option agreement with Apceth had been discontinued.

Cynata said it "continues to work with its development, commercialization and research partners to advance Cymerus to patients in areas of unmet need, as well as to seek opportunities to expand its pipeline in cancer and other therapeutic areas that may benefit from stem cell therapy".

The company said it had filed a patent application with IP (intellectual property) Australia (formerly the Patent and Trademark Office) that would cover the therapeutic use of the Cymerus technology in the treatment of adverse reactions associated with chimeric antigen receptor T-cell (CAR-T) immunotherapy.

Cynata chief executive officer Dr Ross Macdonald told Biotech Daily the application was titled 'Method for Treating a Side Effect of Chimeric Antigen Receptor (CAR) T Cell Therapy' and would provide coverage until April 2038.

Cynata said the application followed an initial provisional patent application on this proposed use of the Cymerus technology, which it filed in April 2017.

The company said that initial mouse study data from the University of Massachusetts Amherst showed Cymerus therapeutic mesenchymal stem cells had "the potential to ameliorate the effects of [cytokine release syndrome] and other related adverse reactions, which can be associated with significant risk to patients and in some cases rapid death".

Cynata head of product development Dr Kilian Kelly said that CAR-T therapies had shown "impressive responses in patients with various types of advanced cancer, in particular, blood cancers such as leukaemia and lymphoma".

"However, CAR-T therapy can lead to potentially fatal and unpredictable adverse reactions, especially cytokine release syndrome, which may severely limit its uptake," Dr Kelly said. "Initial pre-clinical data suggest our Cymerus mesenchymal stem cells may play an important role in managing the toxic side effects of CAR-T therapy, which, in turn, could substantially increase its utility and improve patient outcomes".

Cynata was up one cent or 0.7 percent to $1.40.

RESPIRI (FORMERLY KARMELSONIX, ISONEA)

Respiri says it has completed "the functional demonstration prototype of its second generation Airsonea wheeze monitor.

Respiri said that with the completion of the recent $3.0 million capital raising and the prototype, it "reiterates its prior milestone timelines that include a planned launch of Airsonea Gen II [by April] 2019".

The company has been attempting to commercialize the technology since listing as Karmelsonix in 2006 (BD: Nov 24, 2006; Jan 23, Aug 6, 2015, Oct 11, 2017).

Respiri fell half a cent or 4.2 percent to 11.5 cents with 4.96 million shares traded.

MMJ PHYTOTECH

MMJ says it has a strategic alliance with the Calgary, Alberta-based Target Capital to share information on marijuana investment opportunities.
MMJ said that Target Capital traded as CBi2 Capital and provided capital and expertize to high growth, early-stage companies in the cannabis industry.
The company said the two would share information on a voluntary, reasonable endeavors basis in relation to an investment opportunity where one was unable to capitalize on it in their own right and believed it might be of interest to the other as a co-investment.
MMJ chief executive officer Jason Conroy said that CBi2's investment criteria and focus was “directly aligned with MMJ's strategic intent to own and build a diversified global cannabis investment portfolio”.
MMJ was up one cent or 2.8 percent to 69 cents.

QUEENSLAND BAUXITE

Queensland Bauxite says that 55 percent subsidiary Medical Cannabis has an agreement for Queensland’s Burleigh Heads Cannabis to import and store medical marijuana.
Queensland Bauxite said that Burleigh Heads had an Australian Office of Drug Control medical cannabis import licence and had approved secure storage facilities.
The company said the memorandum of understanding provided the terms for import and storage services and provided Medical Cannabis “immediate access to the required Australian licences and secured storage facilities” required to import its Canntab pills.
Queensland Bauxite fell 0.2 cents or 3.7 percent to 5.2 cents with 102.9 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering’s annual general meeting passed all resolutions but with 12.7 percent opposition to the issue of 135,198 options to chief executive officer Dr Stephen Snowdy.
In the notice of meeting, Visioneering said that Dr Snowdy would be entitled to up to 30 percent of his base salary in 2017 in options on a pro rata basis for nine months, pending achievement of key performance indicators.
The company said that on a base salary of $US360,000 Dr Snowdy would be entitled to $US81,000 in options and with 45 percent of key performance indicators achieved would be entitled to $US36,450 in options with a maximum of 135,198 options.
Visioneering said that the options would be exercisable at the 10-day volume-weighted average price to three days after publishing the annual report, vesting over four years.
The company did not specify an end date for the options.
Today, Visioneering said the grant of options resolution received 101,089,571 votes (87.3%) in favor and 14,701,075 votes (12.7%) “abstaining”.
According to the notice of meeting, abstentions count as a vote against the proposal to issue Dr Snowdy the options, along with abstentions on the re-election of directors.
The company said that directors Jean Franchi and Tom Dooley were elected with more than 113 million votes in favour and 2.5 million votes against, while the 10 percent placement capacity was supported by more than 113 million votes, opposed by 1.9 million votes and had 687,688 abstentions.
Visioneering said that it had 197,058,646 shares outstanding, meaning that the opposition to Dr Snowdy’s options amounted to 7.5 percent of the company’s total shares on issue, sufficient to requisition extraordinary general meetings.
Visioneering was up four cents or 9.3 percent to 47 cents.

ADMEDUS

Admedus will vote to ratify the issue of a warrant over 4,938,799 shares relating to last year's loan and issue 1,435,630 options to chief executive officer Wayne Patterson.
Last year, Admedus said the San Francisco-based Partners for Growth provided "a secured debt facility" up to $10,000,000 consisting of a $5,000,000 "revolving line-of-credit" at an interest rate of 9.75 percent and a $5,000,000 term loan at an interest rate of 11.75 percent repayable in 36 months, along a seven-year warrant, or option, for the issue of 4,938,799 shares exercisable at 25 cents a share (BD: Oct 26, 2017).
Today, the company said it proposed to issue Mr Patterson 1,435,630 options exercisable at 37 cents each within 10 years of issue.
Admedus said the options were the "result of certain financial performance indicators being achieved in 2017 … [and if not approved] the company would be required to compensate Mr Paterson for the cash equivalent of the determined value of the 2017 options one month after the annual general meeting".
The company said that shareholders would also vote to adopt the remuneration report, re-elect director Mathew Ratty and approve the 10 percent placement facility.
The meeting will be held at the office of Jones Day, Level 31, Riverside Centre, 123 Eagle Street, Brisbane, Queensland on May 24, 2018 at 11am (AEST).
Admedus fell one cent or 2.9 percent to 33.5 cents with 2.5 million shares traded.

BTC HEALTH (FORMERLY BIOTECH CAPITAL)

Windarri Investments says it has ceased its holding in BTC Health selling 5,000,000 shares for $1 million to BTC chairman Dr Richard Treagus and director Peter Jones.
In January, BTC said it would sell its wholly-owned consulting business Biointelect Pty Ltd for $700,000 to the Herz Family Trust (BD: Jan 22, 2018).
Today, the Sydney based Windarri, acting for the Herz Family Trust, said it sold the shares off-market on April 20, 2018.
In a substantial shareholder notice, Dr Treagus and his wife Karen Treagus said they acquired 4,000,000 shares for $800,000 today and with other purchases held 22,237,698 shares or 17.07 percent of the company.
In a director's interest statement Mr Jones said he acquired 1,000,000 shares for $200,000 and held a total of 15,711,823 shares.
BTC Health was untraded at 20.5 cents.

BARD1 LIFE SCIENCES

Credit Suisse Australia on behalf of Credit Suisse Group AG says it has become a substantial shareholder in Bard1 with 42,340,003 shares (5.11%).
The substantial shareholder notice said that Credit Suisse bought shares between January 24 and April 13, 2018 with the single largest purchase 40,000,000 shares for $600,000 or 1.5 cents a share.
Bard1 was up 0.3 cents or 20 percent to 1.8 cents with 67.1 shares traded.

THE HYDROPONICS COMPANY

Hydroponics has requested a trading halt "pending an announcement to the market regarding a material acquisition".
Trading will resume on April 24, 2018 or on an earlier announcement.
Hydroponics last traded at 61 cents.

GI DYNAMICS

In a US Securities and Exchange Commission filing GI Dynamics says it “terminated the employment” of Brian Callahan and Houry Youssoufian.

GI Dynamics said that Mr Callahan was the chief compliance officer and Mr Youssoufian was the head of finance and accounting and their terminations would be effective on May 15, 2018.

“Both terminations were the result of a streamlining of operating functions as part of the company’s ongoing efforts to reduce expenses,” the company said.

GI Dynamics said it had appointed Dave Bruce as the principal accounting and financial officer effective immediately.

The company said that Mr Bruce had been the finance director since April 2018 and was previously the general accounting manager.

GI Dynamics said that Mr Bruce had more than 15 years of accounting experience in the pharmaceutical, health and fast casual restaurant industries.

The company said that Mr Bruce held and Bachelor of Science in Accounting and a Master of Business Administration from Boston’s Northeastern University.

GI Dynamics was untraded at 2.6 cents.