Biotech Daily

Wednesday April 11, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: OPTISCAN UP 14%; IMMUTEP DOWN 7%**

*** LIVING CELL RETAINS NTCELL, PERICYTE PROGRAMS, CUTS COSTS**

*** VIRALYTICS: 'THREE TRIALS DATA CONTINUES TO ENCOURAGE'**

*** BIONOMICS PHASE II BNC210 FOR PTSD TRIAL RECRUITED**

*** RACE APPOINTS DURBIN FOR BISANTRENE NPP DISTRIBUTION**

*** CYNATA GRANTED US PATENT FOR CYMERUS**

*** MGC $5m PLACEMENT, MALTA MARIJUANA FACTORY CONTRACT**

*** MMJ PHYTOTECH RENAMES AS MMJ, OPERATIONS UPDATE**

*** G MEDICAL REJECTS ANALYST REPORT**

*** AUSTRALIAN ETHICAL TAKES 13% OF ANTISENSE**

*** REGAL FUNDS TAKE 7% OF MEDIBIO**

*** SAMUEL TERRY, FRED WOOLLARD TAKE 6% OF ACRUX**

*** ALL CHANGE AT PHYLOGICA; DR HOCKINGS 15%, ALAN TRIBE 19.9%**

MARKET REPORT

The Australian stock market fell 0.48 percent on Wednesday April 11, 2018 with the ASX200 down 28.3 points to 5,828.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and four were untraded.

Optiscan was the best on no news, up 0.9 cents or 13.6 percent to 7.5 cents with 119,464 shares traded. Acrux climbed 8.6 percent; Actinogen was up 6.7 percent; Compumedics and Mesoblast improved more than five percent; Bionomics, LBT, Oncosil, Pharmaxis and Polynovo were up three percent or more; Medical Developments and Telix rose more than two percent; Ellex, Neuren, Starpharma and Volpara were up one percent or more; with CSL and Viralytics up by less than one percent.

Immutep led the falls, down 0.2 cents or 7.4 percent to 2.5 cents with 5.0 million shares traded. Dimerix and Uscom fell more than four percent; Avita and Nanosonics lost more than three percent; Airxpanders shed 2.8 percent; Clinuvel and Orthocell were down more than one percent; with Cochlear, Impedimed, Opthea, Pro Medicus and Sirtex down by less than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says it will advance research and development projects, minimizing cash burn and maximize the number and quality of opportunities for near term revenue.

Living Cell said that it had focused on developing a strategy to make the best use of its expertise, assets, partnerships and funds.

Last year, the company's share price fell as much as 89 percent on news that its 18-patient, phase IIb trial of NTCell encapsulated pig choroid plexus brain cells showed no statistical efficacy for Parkinson's disease (BD: Nov 10, 2017).

In December, Living Cell said that long-term data from its four-patient, phase I/II trial showed improvements in some patients and NTCell for Parkinson's would remain its primary focus (BD: Dec 21, 2017).

Today, the company said that by building on established research partnerships and opening more research fronts it was "able to increase and diversify our targets and reduce our dependency on the outcome of any single research program".

Living Cell said that it had regulatory and ethics approvals to follow all patients in the phase IIb trial at 12, 18, and 24 months post implant, which was "now an open study which allows interim analysis of data", concluding in May 2019.

"If, at any time, we get efficacy data that supports a regulatory submission, we can discuss that immediately with the regulators," Living Cell said.

The company said that it had signed a further research contract with the University of Auckland Centre for Brain Research for its pericyte protective agent program, with Prof Mike Dragunow and Prof Margaret Brimble furthering their research on the chemical secretions of NTCell.

Living Cell said the research project was based on earlier studies which showed that chemical secretions of NTCell protected human brain pericytes from injury.

The company said that pericytes were cells that lined the capillaries in brains and played vital roles in maintaining a healthy blood supply to the brain and maintained the blood-brain barrier, which prevented potential toxins from entering the brain.

Living Cell said that pericyte protective agents had the potential to protect the blood-brain barrier, which degenerated in diseases such as Alzheimer's disease and motor neurone disease.

The company said it had signed non-disclosure agreements and memoranda of understanding that enabled it "to continue due diligence on other product opportunities that are near to being ready for first-in-man clinical studies" and it intended to identify two projects for investigation and investment.

Living Cell said it had an interest in its Diabecell encapsulated porcine Islets of Langerhans for type I diabetes, which it had sold to the Otsuka Pharmaceutical Factory but retained an exclusive licence to commercialize the product in Australia, Argentina and New Zealand, if and when it was eventually approved by the US Food and Drug Administration.

The company said it had restructured, reducing staff to reduce the cash burn.

Living Cell said that Dr Janice Lam had been appointed head of operations including research and development and Daya Uka had been appointed head of finance, information technology and corporate services, with contracted consultants to provide expertize on research projects as required.

The company said that the reduced overheads, cash received from the Diabecell joint venture sale, with the finance raised last year and the grant from Callaghan Innovation gave it a three-year cash runway to achieve a revenue-generating endpoint from any research and development initiatives.

Living Cell was up 0.1 cents or 4.8 percent to 2.2 cents.

VIRALYTICS

Viralytics says that 16 of 27 patients in its phase Ib Capra trial for late-stage melanoma had a preliminary best overall response rate with disease control for 22 patients.

Viralytics said that the data from its ongoing Capra, Mitci and Keynote-200 clinical studies assessing Cavatak in combination with cancer immunotherapy agents was presented at the International Oncolytic Virus Conference in Oxford, England, April 10 to 13, 2018, by the Royal Surrey County Hospital's Prof Hardev Pandha.

In February, Merck Inc (or Merck Sharp and Dohme outside the US and Canada) said it would acquire Viralytics for $502 million (BD: Feb 22, 2018).

Viralytics said the patients were treated with a combination of intra-lesional Cavatak, or Coxsackievirus A21 and pembrolizumab, marketed as Keytruda.

The company said that the response rates of 59.3 percent and 81.5 percent, respectively, exceeded the published rates for either agent alone, with Cavatak achieving 28 percent and Keytruda 33 percent.

Viralytics said the study had enrolled 31 patients.

The company said that in the phase Ib Mitci trial, the combination of intra-lesional Cavatak and ipilimumab, marketed as Yervoy, was well tolerated and had activity in advanced melanoma patients whether or not they have been previously treated with anti-PD-1 therapies such as Keytruda.

Viralytics said that of the 16 patients not been previously treated with Keytruda or other anti-PD-1 therapies, the response rate was 50 percent, and in the nine patients who failed earlier single line anti-PD-1 treatment, there were responses in three of nine patients, which was "promising … in a setting where there is a high unmet need for new therapies".

The company said that the Mitci trial had enrolled 46 patients.

Viralytics said that it had competed enrolment for the 85-patient Keynote-200 phase I trial of Cavatak with Keytruda for advanced non-small cell lung cancer or metastatic bladder cancer.

The company said the Keynote-220 trial was a collaboration with Merck.

Viralytics said that systemic administration of Cavatak with pembrolizumab mediated encouraging clinical signals of activity.

The company said that of the 45 patients naïve to prior checkpoint therapy, four were not evaluable for target lesion response assessment due to withdrawal of consent, early disease progression or study discontinuation.

Viralytics said that for the remaining 41 evaluable patients, there were unconfirmed target lesion responses in five of 16 non-small cell lung cancer and seven of 25 metastatic bladder cancer patients, with 16 of the 41 patients remaining on the study and being monitored for response.

The company said that 28 percent and 56 percent, respectively, of the advanced bladder and non-small cell lung cancer patients had received two or more prior therapies.

Viralytics said that prolonged stable disease was the best response observed to date in 16 evaluable patients previously treated with immune checkpoint inhibitors.

The company said that the Cavatak with pembrolizumab combination was generally well tolerated, with seven of 85 patients displaying treatment related grade 3 adverse events and no grade 4 or grade 5 treatment related adverse events.

Viralytics said that initial tumor biopsy data before and after the Cavatak and pembrolizumab administration, showed "promising changes in the levels of the important biomarker PD-L1, including a notable intra-tumoral induction of PD-L1 at day 15 relative to baseline in patients with negative or low baseline PD-L1 treated with Cavatak and pembrolizumab.

Viralytics was up half a cent or 0.3 percent to $1.69.

BIONOMICS

Bionomics says its 192-patients 'Restore' phase II safety and efficacy trial of BNC210 for post-traumatic stress disorder is fully recruited, with results expected this year.
Bionomics said the randomized, double-blind, placebo-controlled trial at sites in the US and Australia had a primary endpoint of a decrease in post-traumatic stress disorder (PTSD) symptoms as measured by the clinician-administered PTSD scale (CAPS-5), with secondary endpoints including a decrease in symptoms of anxiety and depression.
Bionomics chief executive officer Dr Deborah Rathjen said that "full recruitment … marks a significant achievement for Bionomics".
Bionomics said it would host key opinion leader meetings on BNC210 for post-traumatic stress disorder in New York on April 13 and in London on April 17, 2018.
In 2012, Bionomics said that the Cambridge Massachusetts-based Ironwood Pharmaceuticals would pay it a $US3 million upfront fee for a licence for its anti-anxiety compound BNC210, in an agreement worth up to $US345 million in upfront and milestone payments and research funding, as well as royalties on sales of products incorporating BNC210 and other related compounds (BD: Jan 22, 2012).
In 2014, Ironwood handed the compound back to Bionomics (BD: Nov 11, 2014).
Bionomics was up two cents or 3.7 percent to 56 cents.

RACE ONCOLOGY

Race says it has appointed Durbin PLC as its Bisantrene distributor for Australia, the UK, Central and Eastern Europe, New Zealand, the Middle East and South Africa.
Race said the London-based Durbin would handle named patient program distribution of Bisantrene for acute myeloid leukaemia.
The company said that Durbin had experience in named patient programs and distributed pharmaceuticals and health care products to 180 countries.
In 2015, Race said Bisantrene was a phase II/III drug trialed in 44 clinical studies and more than 2,000 patients, which did not have the cardiac toxicities of other anthracycline drugs used as chemotherapy for cancer and had previously been approved in France for acute myeloid leukaemia, but never launched (BD: Aug 27, 2015; Jul 11, 2016).
Race said it hoped to establish named patient sales in France, Italy, Turkey and Korea.
Race chief executive officer Peter Molloy said the agreement "significantly expands our [named patient program] opportunity for Bisantrene".
Race was up 1.5 cents or 4.4 percent to 35.5 cents.

CYNATA THERAPEUTICS

Cynata says the US Patent and Trademark Office has granted a further patent that covers "aspects of [its] propriety Cymerus platform".
Cynata said the patent application, titled 'Methods and material for haematoendothelial differentiation of human pluripotent stem cells under defined conditions' was owned by the University of Wisconsin Madison's Wisconsin Alumni Research Foundation, licenced to Cynata and would provide coverage until January 24, 2035.
Cynata chief executive officer Dr Ross Macdonald said the company was "delighted that the US Patent and Trademark Office has granted this additional patent around our core Cymerus technology".
In March, Cynata said the US Food and Drug Administration had granted orphan drug designation for CYP-001 for graft versus host disease (BD: March 28, 2018).
Cynata was up three cents or 2.2 percent to $1.385.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has raised $5,000,000in a placement at seven cents a share, to fund its new production and cultivation facility in Malta.
MGC said the “oversubscribed” placement was led by Bell Potter and received support from new and existing shareholders, including the Merchant Opportunities Fund.
The company said that the Government of Malta had awarded it a contract to build the 4,000 square metre medical cannabis production and cultivation facility.
MGC said the contract required it to spend a minimum of about $6,500,000 over the first three-year term on the construction and operations of the facility and to employ a minimum of 25 Maltese people as part of the local workforce.
The company said the marijuana produced at the facility would be used in the production of good manufacturing practice pharmaceutical products and would “complete the board’s strategic plan to establish a fully vertically integrated medical cannabis seed to sale operation in the European Union”.
MGC was up 0.9 cents or 12.0 percent to 8.4 cents with 9.5 million shares traded.

MMJ PHYTOTECH

MMJ Phytotech says it has renamed itself MMJ and 34.4 percent subsidiary Harvest One is conducting phase II trials in paediatric epilepsy and multiple sclerosis pain.
MMJ said that Harvest One’s wholly-owned subsidiary, the Switzerland-based Satipharm’s Gelpell cannabidol capsules would be assessed in the two trials.
The company said the first study, conducted by Israel’s Novatrial was underway to assess the efficacy of the cannabidol capsules on child epilepsy, with patients expected to finish treatment by mid-2018 and the final report to be completed by the end of the year.
MMJ said the second study would assess the safety and efficacy of the capsules for multiple sclerosis pain and spasticity but the trial was on hold pending approvals.
The company said that beyond the two phase II trials it was “highly unlikely” that wholly-owned subsidiary Phytotech Therapeutics would continue the program without a funding partner, due to a significant time and investment commitment.
MMJ said it was open to expressions of interest for partnerships to develop, manufacture and market medical cannabis products based on “pro-nano liposphere” patents that it had licenced from the Israel-based Hebrew University’s Yissum Research Development Co.
The company said that Phytotech’s head of research and development Dr Hagit Sacks would leave the company at the end of July 2018, with MMJ chief operating officer Catherine Harvey assuming management responsibilities.
In 2015, Phytotech said it had merged with the Vancouver, British Columbia-based MMJ Bioscience to form MMJ Phytotech (BD: May 26, Jul 28, 2015).
MMJ fell half a cent or 1.4 percent to 35.5 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical says it has not approved a TMT Analytics analyst report it commissioned, which has been published and withdrawn.
G Medical said the report contained prospective financial information regarding production and sales targets for its products.
In March, the company responded to an ASX query confirming it had not achieved a number of milestones it had expected to reach in previous announcements, such as the trial of its smartphone case with vital sign sensors (BD: March 28, 2018).
G Medical fell two cents or six percent to 31.5 cents.

ANTISENSE THERAPEUTICS

Australian Ethical Investment says it has become a substantial shareholder in Antisense with 24,233,911 shares or 13.04 percent of the company.
The Australian Ethical substantial shareholder notice said it acquired the shares on April 5, 2018 for $581,614 or 2.4 cents a share.
Last week, Antisense said it had raised $581,614 in a placement to Australian Ethical and would conduct a rights issue at the same price for a further $4,459,040 (BD: Apr 3, 2018).
Antisense fell 0.2 cents or 6.25 percent to three cents.

MEDIBIO

Regal Funds Management says it has increased its substantial holding in Medibio from 11,185,393 shares (5.74%) to 14,225,816 shares (7.03%).
The Sydney-based Regal Funds substantial shareholder notice said it bought and sold shares between December 19, 2017 and April 9, 2018 with the single largest purchase 2,889,377 shares for $433,499 or 15 cents a share.
Medibio was up 1.5 cents or 8.3 percent to 19.5 cents.

ACRUX

Samuel Terry Asset Management and director Fred Woollard say they have become substantial shareholders in Acrux with 10,234,371 shares or 6.15 percent.
The Sydney based Samuel Terry and Mr Woollard said they acquired shares between December 7, 2017 and April 6, 2018 with the single largest purchase 2,133,823 shares for $343,289 or 16.09 cents a share.
Acrux was up 1.5 cents or 8.6 percent to 19 cents.

PHYLOGICA

Phylogica says Alan Tribe and Dr Rohan Hockings have been appointed chair and chief executive officer, respectively, replacing Stephanie Unwin and Michael Williams.
Phylogica said Ms Unwin would resign as both chair and chief executive officer, following the next board meeting on April 27, 2018, having been appointed chair in 2016 and chief executive officer last year, with director Mr Williams appointed a director earlier this year (BD: Apr 11, 2016; Jun 20, 2017; Jan 21, 2018).
Phylogica said Mr Tribe had increased his shareholding in the company to 19.9 percent "to accompany his appointment as chairperson".
In a separate announcement, director Dr Bernard Hockings said he had decreased his substantial shareholding in the company from 582,924,185 shares (27.50%) to 317,924,185 shares (14.86%), having sold 265,000,000 shares for $7,950,000 or three cents a share on April 10, 2018 in an off-market transfer.
Australian Land Pty Ltd and Mr Tribe said they had increased their substantial shareholding in Phylogica from 160,776,247 shares (7.52%) to 425,776,247 shares (19.91%), having bought the 265,000,000 shares for $7,950,000 on April 10, 2018.
Phylogica said that Dr Bernard Hockings was Dr Rohan Hockings' father.
Phylogica was up half a cent or 17.9 percent to 3.3 cents with 7.1 million shares traded.