Biotech Daily

Monday September 8, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 20%, CELLMID DOWN 21%**

*** GENETIC TECHNOLOGIES DR MERVYN JACOBSON PLEADS 'NOT GUILTY'**

*** OLIVIA NEWTON-JOHN INSTITUTE OPENS, VICTORIA GRANTS $4.5m**

*** US ARMY APPROVES NEUREN PHASE II CONCUSSION TRIAL**

*** INVION 30mg INV103 INEFFECTIVE FOR MILD LUPUS, STRONGER DOSE**

*** BLUECHIIP PLACEMENT RAISES $1.1m, SHARE PLAN FOR MORE**

*** PHARMAXIS: 'BRONCHITOL BENEFIT FOR HIGH RISK BRONCHIECTASIS'**

*** IMUGENE APPOINTS VIENNA UNIVERSITY FOR HER-VAXX PRE-CLINICAL**

*** VIRALYTICS APPOINTS PETER TURVEY, MALCOLM MCCOLL DIRECTORS - REPLACING DR PHILLIP ALTMAN AND PETER MOLLOY**

*** IMPEDIMED APPOINTS DR FRANK VICINI CHIEF MEDICAL OFFICER**

*** BIOPROSPECT HEART RATE DEPRESSION TEST, DR JAMES CAMPBELL**

MARKET REPORT

The Australian stock market fell 0.39 percent on Monday September 8, 2014 with the S&P ASX 200 down 21.7 points to 5,577.0 points. Ten of the Biotech Daily Top 40 stocks were up, 13 fell, 12 traded unchanged and five were untraded.

Optiscan was the best, up 0.7 cents or 20 percent to 4.2 cents with 75,500 shares traded, followed by Oncosil up 12.5 percent to 13.5 cents with 2.4 million shares traded. Antisense, Compumedics and Nanosonics climbed four percent or more; Pharmaxis was up 3.8 percent; Alchemia, Benitec and Starpharma rose more than two percent; Clinuvel was up 1.7 percent; with Resmed up 0.35 percent.

Cellmid led the falls, down 0.7 cents or 21.2 percent to 2.6 cents with 27.5 million shares traded, followed by Prana down 12.1 percent to 29 cents with 4.3 million shares traded. Acrux lost 5.3 percent; Bionomics, Biotron, Mesoblast and Neuren fell more than four percent; Admedus, GI Dynamics and Impedimed were down more than three percent; Analytica and Atcor shed more than two percent; Cochlear and CSL were down more than one percent; with Sirtex down 0.8 percent.

GENETIC TECHNOLOGIES

Genetic Technologies founder Dr Mervyn Jacobson has pleaded not guilty to two counts of conspiracy and 33 counts of market manipulation in the Victoria Supreme Court.

Genetic Technologies former chief executive officer and formerly the company's largest shareholder pleaded "not guilty" as Justice Stephen Kaye's clerk read out each of the 35 charges.

Dr Jacobson was charged with two counts of conspiring to take part in transactions which were likely to have the effect of creating an artificial price or maintaining a price at a level that is artificial, contrary to Section 11.5 of the criminal code and Sections 1041A and 1311 of the Corporations Act 2001.

Dr Jacobson was charged with 33 counts of taking part in transactions that were likely to have the effect of creating an artificial price or maintaining a price at a level that that is artificial, contrary to Section 1041A and Section 1311 of the Corporations Act 2001.

Justice Kaye told the 50-strong panel of potential jurors that the charges related to events between May and November 2006 and that Dr Jacobson of New Street, Brighton, was a medical practitioner and had conducted research in genetics and owned about 40 percent of Genetic Technologies.

Justice Kaye said that the co-accused in the conspiracy charges were Dr Jacobson's daughter Tamara Newing, formerly Tamara Milstein, and her husband Geoffrey Newing, formerly of Toorak now residing in Mount Martha, along with former ABN Amro Morgans employee Richard John Wade and former Bell Potter adviser Rocco Musumeci.

Justice Kaye said that the circumstances of the case were that in March 2005 Dr Jacobson exercised options for shares in Genetic Technologies and borrowed "a substantial sum" from Opus Prime and Chimera Capital, in agreements that stipulated that if the price of the shares fell below a particular level Dr Jacobson would need to provide further security. Justice Kaye said that the price did fall and between May and November 2006 Dr Jacobson and other persons mentioned bought shares so the closing price would be above the level determined.

Justice Kaye said that the prosecution case was that Dr Jacobson intended to avoid the call for additional security and that Tamara Newing and Geoff Newing bought shares as well as through Palomine Pty Ltd, a company owned by Geoff Newing, to set or maintain a closing price at a level above the requirement for a call of increased security.

Justice Kaye said that Dr Jacobson bought shares in Genetic Technologies through the Colorado-based XY Inc, which he controlled through a large shareholding.

Justice Kaye said about 16 witnesses would be called to give evidence including Mr Wade and Mr Musumeci, former Genetic Technologies chief financial officer Thomas Howitt, current Genetic Technologies director Dr Mervyn Cass and executive assistant Karen Phillips, along with staff and former staff from the Australian Securities and Investments Commission, Bell Potter, Chimera Capital, NAB, ABN Amro Morgans and XY Inc.

The 33 charges of market manipulation related to the purchase of shares by XY Inc in parcels from 10,000 shares to 100,000 shares, but mostly of 20,000 to 60,000 shares at about 34 cents a share in September 2006.

Justice Kaye said that 14 jurors would be empanelled instead of the usual 12 due to the expected length of the trial, with a secret ballot held to reduce the number if more than 12 were available at the time of retiring to consider the verdicts.

The Commonwealth Director of Public Prosecutions legal team is led by Jeremy Rapke, QC, with Dr Jacobson's defence led by Dr Joshua Wilson, QC.

Justice Kaye said that trial was likely to run for eight weeks and would be conducted in the County Court building where access to computer technology was easier.

Genetic Technologies was unchanged at 2.5 cents.

VICTORIA GOVERNMENT

The Victoria Government says the Olivia Newton John Cancer Research Institute officially opened at Austin Hospital today with further funding of $4.5 million for cancer research.
The State Government said that the $4.5 million was part of $42 million invested in the Institute, which Premier Dr Denis Napthine said would "enable the Olivia Newton John Cancer and Wellness Centre to access the world's best cancer research through the $1 billion Victorian Comprehensive Cancer Centre".
"This forms part of the Victorian Coalition Government's $139 million investment in the Olivia Newton John Cancer and Wellbeing Institute," Dr. Napthine said.
"Importantly, the research conducted here will make a real difference in the lives of Victorians and all Australians who are fighting cancer," Dr Napthine said.
A media release from the Premier said that the Institute would occupy three floors of dedicated research space in the Olivia Newton-John Cancer and Wellness Centre and operate as a not-for-profit, independent, medical research institute.
The Coalition Government said that since its election in 2010, it had invested more than $400 million in health and medical research, including $87 million in teaching and development grants, $27 million for biotechnology industry development and $18 million for the Global Health Melbourne plan.

NEUREN PHARMACEUTICALS

Neuren says the US Army has approved its 132 patient, double-blind, placebo-controlled phase II trial of NNZ-2566 for concussion, or as mild traumatic brain injury.
Neuren said that about 132 subjects with concussion would be enrolled and receive treatment with either NNZ-2566 or placebo for seven days post-injury.
The company said that two dose levels of orally administered NNZ-2566 were being tested, with a number of measures assessing physical and emotional symptoms and cognitive function to be analyzed, together with safety and tolerability measures.
Neuren said that it expected top-line results from the trial by the end of 2015.
The company said that there was no approved drug available for acute concussion and the trial was "a world-first, commercial-sponsored, clinical trial of a potential new medicine in this therapeutic area" and the health and economic impacts of concussion were increasingly recognized, with current initiatives mainly focused on diagnosis, rather than on intervention to address the symptoms of injury.
Neuren said that NNZ-2566 had the potential to address cellular and molecular changes in the brain that were known to be caused by concussion.
The company said that in animal models, NNZ-2566 has been shown to inhibit neuro-inflammation, normalize microglial function, restore synaptic signalling and increase IGF-1 expression in the brain.
Neuren said the trial was being conducted with the US Army's 82nd Airborne Division at Fort Bragg, North Carolina, as a continuation of the collaboration on the development of potential therapies for traumatic brain injury.
The company said that the major sporting codes for which concussion had serious health and economic consequences were also a key target market and the profile of the military population for the trial was similar to the profile of athletes in the relevant sports.
Neuren executive chairman Dr Richard Treagus said that "given the known properties of NNZ-2566, we are hopeful that this ground-breaking trial can demonstrate the potential for Neuren's drug to help mitigate the serious ramifications of concussions, which are now being recognized in civilian, sporting and military communities around the world".
Neuren fell 0.5 cents or 4.8 percent to 10 cents with 6.05 million shares traded.

INVION

Invion says interim data from its phase II clinical trial of INV103, or Chaperonin 10 for lupus shows the drug is safe but with no statistically significant pattern of response.

Invion said that the first systemic lupus erythematosus cohort patients received a twice-weekly intravenous dose of either 10mg INV103 or placebo and second cohort patients received a twice-weekly intravenous dose of 30mg INV103 or placebo.

The company said that data analyzed included a range of serum biomarkers, blood chemistries, adverse drug events, anti-drug antibodies, vital signs, and signs and symptoms of lupus.

Invion said that in the 10mg cohort, neither serum biomarkers nor stimulated cells showed any statistically significant pattern of response to INV103.

The company said that in the 30mg cohort, serum biomarkers showed no statistically significant cohort-wide response to treatment, “due to baseline values at or near the normal range”.

Invion said that safety data from the first two cohorts of the study demonstrated a safety profile supportive of testing higher doses in the ongoing phase II trial and data from both cohorts showed no pattern of adverse events.

The company said that based on the safety profile generated from these results, the protocol had been advanced to dosing mild lupus patients at 100mg twice-weekly.

Invion research and development executive vice-president and chief medical officer Dr Mitchell Glass said that it was “not unexpected that lupus patients with mild disease may not have a baseline abnormality in these biomarkers and hence cannot show a response to treatment”.

“It was important for us to establish this safety profile in mild lupus patients and now we look forward to leveraging this understanding into the final cohorts of the study, which include significantly higher doses of INV103, and also patients with more severe disease,” Dr Glass said.

“While we will continue to collect valuable safety and pharmacokinetic data in mild patients, results to date have allowed us to open a dialogue with the [US Food and Drug Administration] to enable us to study [systemic lupus erythematosus] patients with more severe disease, including the renal disorder associated with [systemic lupus erythematosus],” Dr Glass said.

“Patients with more severe lupus have higher levels of the biomarkers that we are examining and accordingly we would hope to see amelioration of these important biomarkers,” Dr Glass said.

Invion fell 1.1 cents or 13.75 percent to 6.9 cents with 4.05 million shares traded.

BLUECHIIP

Bluechiip says it has raised $1.1 million through a placement at 10 cents a share and hopes to raise more funds through a share plan at the same price.

Bluechiip said each new share came with an attaching option exercisable at 13 cents by March 31, 2015.

The company said the proceeds would be used for working capital.

Bluechiip said that the record date for the share plan was September 5, the plan would open on September 11 and close on September 25, 2014, with shares available in parcels of up to $15,000, although those who participated in the previous share plan could only apply for up to an aggregate of $15,000 in total shares across the two plans (Jun 3, 2014).

Bluechiip fell two cents or 14.8 percent to 11.5 cents with 4.3 million shares traded.

PHARMAXIS

Pharmaxis says that a new data analysis from its trial of Bronchitol for bronchiectasis shows benefit for patients at higher risk of further exacerbations.

In April, Pharmaxis share price fell 52.4 percent on news that its phase III trial of Bronchitol for bronchiectasis did not meet its primary endpoint of exacerbation reduction (BD: Apr 24, 2014).

Today the company said that the data would be presented at the European Respiratory Society meeting in Germany from September 6-10, 2014.

Pharmaxis said that the UK Newcastle University senior lecturer in respiratory medicine Dr Anthony de Soyza examined a higher risk sub-group from the trial who, despite best standard of care, continued to suffer breathlessness even at rest and frequent exacerbation.

The company said that in this subgroup of patients at higher risk of further exacerbations, Bronchitol demonstrated both clinically important and significant improvements in exacerbation rate, antibiotic use and total scores on top of existing best standard of care over a 12 month period.

Pharmaxis said that the study authors concluded the post-hoc findings suggested a greater effect from Bronchitol in higher risk patients than observed in the broader non-cystic fibrosis bronchiectasis population studied.

The company said that although Bronchitol failed to meet its primary endpoint of an improvement in bronchiectasis exacerbation rate, significant improvements in time to first exacerbation, days of antibiotic use and other measures were seen.

Pharmaxis chief executive officer Gary Phillips said that bronchiectasis was a disease "with very few treatment options and showing a clear treatment effect in such a heterogeneous patient population has proved difficult".

"The benefit shown in this subgroup of our B305 phase III study is therefore quite interesting," Mr Phillips said.

"While Pharmaxis is not currently planning to progress the B305 data with another study, the authors of this new analysis noted that the positive findings should encourage further investigation," Mr Phillips said.

Pharmaxis was up 0.2 cents or 3.8 percent to 5.5 cents with 1.1 million shares traded.

IMUGENE

Imugene says that the Medical University of Vienna will conduct pre-clinical immunology experiments in preparation for the 2015 phase II clinical trials of Her-Vaxx.

Imugene said that the Medical University of Vienna's Prof Ursula Wiedermann and her group would focus on peptides and peptide-incorporated influenza virosomes to be used in the Her-Vaxx phase II clinical trial.

The company said that Prof Wiedermann was a member of its scientific advisory board and was the principal investigator for the preclinical development of Her-Vaxx and led the design of the Her-Vaxx phase II study for gastric cancer due to begin in 2015.

Imugene chief executive officer Charles Walkeraid that the research would support the phase II trial design and investigational new drug application to the US Food and Drug Administration.

The company said that Prof Wiedermann performed the phase I Her-Vaxx clinical trial in metastatic breast cancer patients with Prof Christoph Zielinski.

Imugene fell 0.1 cents or 6.25 percent to 1.5 cents with 1.2 million shares traded.

VIRALYTICS

Viralytics says it has appointed former CSL executive Peter Turvey as a director, along with chief executive officer Dr Malcolm McColl.
Viralytics said that Mr Turvey had more than 30 years' experience in the biotechnology sector, 20 of which were spent at CSL in roles including group general counsel and executive vice president licensing.
The company said that Mr Turvey was a principal of science and technology advisory services firm Foursight Associates and a non-executive director of Ausbiotech, Starpharma, Admedus and Agriculture Victoria Services.
Viralytics said that at CSL, Mr Turvey was integral to the company transforming from a Government-owned organization to a multi-billion dollar global biopharmaceutical company and was involved in the acquisitions and divestments of businesses.
The company said that Mr Turvey was responsible for licencing and the protection of the company's intellectual property as well as corporate risk management, playing a key role in the establishment of the Gardasil vaccine licence to Merck & Co and the licencing of the Iscomatrix adjuvant platform technology to vaccine manufacturers.
Viralytics said that directors Dr Phillip Altman and Peter Molloy would retire as directors following seven and six years service to the company, respectively.
Viralytics was unchanged at 26.5 cents with 7.8 million shares traded.

IMPEDIMED

Impedimed says it has appointed Dr Frank Vicini as its first chief medical officer.
Impedimed said that would provide oncology expertise and leadership and advise on business development and strategy, and support medical education and publication.
The company said that Dr Vicini was a radiation oncologist with experience in cancer clinical trial design and implementation and he had held multiple academic appointments, authored more than 200 peer-reviewed articles and had been involved in numerous clinical studies focusing on cancer treatment.
Impedimed said that Dr Vicini was the co-investigator of its L-Dex post-approval clinical study and the principal investigator of several US National Institutes of Health trials with the goal of improving therapeutic outcomes for all stages of breast cancer, reducing treatment times and minimizing toxicities of healthy tissues and vital organs.
Impedimed fell 1.5 cents or 3.3 percent to 44 cents.

BIOPROSPECT

Bioprospect says it will acquire Invatec for its heart rate variability technology for mental health diagnoses and has appointed Dr James Campbell as a director.
Dr Campbell was formerly an executive with Chemgenex and is a director of Invion.
Bioprospect said that Chris Indermaur had been appointed as the incoming chairman, with Dr Matt Mesnick as chief medical officer, with the heart rate variability inventor Prof Hans Stampfer appointed as a member of the advisory board, with Stephen Pearce to chair the advisory board with Prof Stampfer and Dr Stephen Addis.
The company said it proposed to raise $4 million at a post-consolidation 30 cents a share, in conjunction with the simplification and a 100-to-one consolidation.
Bioprospect fell 0.1 cents or 20 percent to 0.4 cents with 131.7 million shares traded.