Biotech Daily

Friday November 8, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GENETIC TECHNOLOGIES UP 15%, ATCOR DOWN 9%**

*** IMMURON IMM-124E 'ALLEVIATES LIVER FIBROSIS IN MICE'**

*** FEDERAL GOVERNMENT $522m FOR 1,177 ARC RESEARCH PROJECTS**

*** ALLIED SHIPS 1st EUROPEAN CARDIOCEL ORDER**

*** VIRALYTICS PREPARES FOR NEW CAVATAK MELANOMA TRIAL**

*** FDA CLEARS IMMURON PHASE II IMM-124-E ASH TRIAL**

*** ANTEO, BBI SOLUTIONS TO INVESTIGATE MIX&GO FOR DIAGNOSTICS**

*** PATRYS 2nd US PATENT FOR PAT-LM1**

*** OSPREY COMPLETES $14m PLACEMENT**

*** BIODIEM DEPARTS THE ASX**

*** BIOTRON AGM ROLLS DIRECTOR BRUCE HUNDERTMARK**

*** UP TO 11% OF ALCHEMIA AGM OPPOSE DIRECTOR OPTIONS**

*** UP TO 24% OF NANOSONICS OPPOSE CHAIRMAN MAURIE STANG**

*** 'THIRD PARTY' AGREES TO PAY BACK PHOSPHAGENICS THEFT**

MARKET REPORT

The Australian stock market fell 0.39 percent on Friday November 8, 2013 with the S&P ASX 200 down 21.3 points to 5,400.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and three were untraded. All Big Caps fell.

Genetic Technologies was best, up 0.9 cents or 15 percent to 6.9 cents, with 2.9 million shares traded, followed by Allied Health up 13.3 percent to 17 cents with 19.0 million shares traded and Patrys up 12.8 percent to 5.3 cents with 158.5 million shares traded. Compumedics climbed 9.8 percent; Circadian was up 4.2 percent; Impedimed was up 3.1 percent; with Anteo, Tissue Therapies and Viralytics up more than two percent.

Atcor led the falls, down 1.5 cents or 9.1 percent to 15 cents with 2.0 million shares traded. IDT lost 8.1 percent; Prana and Psivida fell more than seven percent; Benitec and Medical Developments fell more than six percent; Bionomics and Cellmid shed five percent or more; Avita, GI Dynamics and Neuren fell more than four percent; Uscom was down 3.2 percent; with Mesoblast, Nanosonics and Prima down more than two percent.

IMMURON

Immuron says that its bovine colostrum-based oral IMM-124E alleviates liver damage and fibrosis in mice.

Immuron said the in-vivo pre-clinical data from the Jerusalem, Israel-based Hadassah-Hebrew University Medical Center was presented as a potential therapeutic for fibrosis at the American Association for the Study of Liver Disease meeting in Washington DC from November 1 to 5, 2013.

The presentation, entitled 'Alleviation of liver damage and hepatic fibrosis by oral administration of IMM-124 colostrums in Carbon tetrachloride (CCl4) model is mediated by decrease of hepatic F4/80 macrophages activation' concluded that "oral administration of IMM-124E exerts an immuno-modulatory effect in mice treated with CCl4".

"The regulatory effect and suppression of F4/80 macrophages was associated with alleviation liver damage and fibrosis in these treated mice," the paper concluded.

The presentation said that hepatic fibrosis development required the coordinated actions of several cell type including Kupffer cells and IMM-124E colostrum or immuno-globulin G-enhanced fraction of enterotoxigenic Escherichia coli colostrum from Immuron exerted "an immunomodulatory effect and alleviates target organ damage in different animal models".

The presentation said that its aim was to determine the efficacy of oral administration of IMM-124E colostrum to mice undergoing treatment with CCl4 to prevent hepatic damage and fibrosis by modulating hepatic F4/80 macrophages.

The Hadassah researches said that liver injury was induced by administration intra-peritonealy of CCl4 and control mice in group A were treated only with IP CCl4, with mice in group B were treated only with oral IMM-124E colostrum and group C were orally treated with IMM-124E colostrums and IP CCl4, with all groups treated for 30 days.

The presentation said that mice were followed for liver injury by a range of standard liver tests and immune-histochemistry.

The results showed that oral administration of IMM-124E was effective with a decrease in liver enzymes noted between the different study groups at day 30 with ALT levels ($P < 0.05$); body weight was different between the groups with near normal weight in the study group C comparing to group B ($p < 0.001$); and Masson's trichrome stain showing higher score of fibrosis in group A compared with group C.

Immuron said that fibrosis was the formation of excess fibrous connective tissue in an organ or tissue during an inflammatory or reparative process, disrupting the normal function of an organ or tissue, which was different from the formation of fibrous tissue as a normal constituent of an organ or tissue.

Immuron said that liver fibrosis was the common scarring reaction associated with chronic liver injury and with protracted damage, fibrosis could progress toward excessive scarring and organ failure, as in liver cirrhosis.

The company said the Hadassah studies showed that its IMM-124E containing bovine colostrum enriched with antibodies reactive to lipopolysacchardies, could be applied for the prophylaxis, treatment or alleviation of fibrosis, particularly, lung fibrosis and liver fibrosis.

Immuron chief executive officer Amos Meltzer said that the number of patients suffering from fibrosis in different organs was difficult to ascertain, but "the results that were presented at the American Association for the Study of Liver Disease meeting support our expectation that IMM-124E is a potential therapeutic for a large range of fatty liver patients including those with fibrosis of the liver".

Immuron was up 0.2 cents or 28.6 percent to 0.9 cents with 5.3 million shares traded.

FEDERAL GOVERNMENT, AUSTRALIA RESEARCH COUNCIL

The Federal Minister for Education Christopher Pyne says Australia's research and innovation sector will receive $522 million for 1,177 Australia Research Council projects.
A media release from Mr Pyne said the funding included 201 projects under the Future Fellowships scheme; 703 projects under the Discovery Projects scheme; 200 projects under the Discovery Early Career Research Award scheme; 63 projects under the Linkage Infrastructure, Equipment and Facilities scheme; and 10 projects under the Discovery Indigenous scheme.
Mr Pyne said the announcement of more than 1,000 new research projects, many with international collaborations, was an significant investment.
"If Australia is continue to produce ground-breaking research outcomes, 'eureka' moments and Nobel laureates, then a strong investment in research is needed," Mr Pyne said.
"The Coalition Government is committed to enabling our researchers to investigate, explore and discover and to deliver outcomes that benefit the nation," Mr Pyne said.
"In the past ARC funding has produced award winning research," Mr Pyne said. "Only last week Prof Ruth Bishop received the Florey Medal for her 1973 discovery of rotavirus and Prof Terry Speed received the 2013 Prime Minister's Prize for Science."
"I am confident that the research funding announced today will in time appear in prizes like these announced last week," Mr Pyne said.
A complete list of all the Australia Research Council grants is available at: http://www.arc.gov.au/pdf/FT13/FT13_outcome_summary_State_and_Org.pdf.

ALLIED HEALTHCARE GROUP

Allied Health says it has received its first European orders for its Cardiocel Adapt-treated bovine cardiac tissue and begun shipment.
Allied said it was the first offshore order for the cardiac patch.
The company said it received Conformité Européenne (CE) mark approval in August clearing the final regulatory hurdle ahead of a launch and marketing of the product in Europe (BD: Aug 26, 2013).
Allied chief executive officer Lee Rodne said that the first sale of Cardiocel in Europe was "a milestone development for both the company and our lead regenerative tissue product".
"Allied is seeking to have Cardiocel used by cardiothoracic surgeon teams across Europe for the repair and reconstruction of cardiac defects in both adults and children," Mr Rodne said.
"We will initially focus our European sales team on the major centers across Europe as we aim to build our market penetration over the next 12 to 36 months," Mr Rodne said.
Allied said that Cardiocel was available for use by surgeons in Australia via an authorized prescriber scheme and had been shown to offer a range of benefits over alternative products including a strong level of regeneration of tissue, lack of cytotoxicity and calcification at the site of repair.
The company said it expected "significant growth in group earnings over the coming 12 months to three years as it continues to grow revenue from its infusion product portfolio and its regenerative tissue programs".
Allied said it planned to expand its regenerative tissue portfolio with additional tissue products for cardiovascular repair and reconstruction, vessel repair and conduits as well as other applications like cellular therapies, hernia and pelvic floor repair.
The company said it continued to progress well with its US Food and Drug Administration 510(K) pre-market application for Cardiocel, with approval expected in 2014.
Allied was up two cents or 13.3 percent to 17 cents with 19.0 million shares traded.

VIRALYTICS

Viralytics says that two more melanoma patients have reached the primary endpoint of its phase II Cavatak trial, encouraging a larger randomized phase II trial.

Viralytics said that the single-arm study met its primary endpoint in September when 10 patients from a total of 54 evaluable patients reached six months of immune-related progression free survival after the first dose of Cavatak (BD: Sep 18, 2013).

Today, Viralytics said that 12 of 35 evaluable patients had reached the six month target.

The company said that nine patients of 16 had reached the 12 month survival point, a rate of 56 percent, with an overall response rate in nine patients from 38 assessable patients

Viralytics said there was “encouraging activity in non-injected metastatic tumors”.

The company said it had enrolled 49 patients with all 54 patients expected to be enrolled by the end of 2013

Viralytics said there had been no reports of drug-related grade three or four or serious adverse events

The company said that the phase II trial of Cavatak in late stage melanoma (Calm) at 11 US sites was investigating the safety and efficacy of intra-tumoral Cavatak or Coxsackievirus A21 in 54 evaluable patients with late stage malignant melanoma.

The Salt Lake City Utah-based Huntsman Cancer Institute lead investigator Dr Robert Andtbacka said that Cavatak “continues to demonstrate very promising anti-cancer activity while being well tolerated in these late stage melanoma patients”.

“Based on the robust interim results further clinical evaluation of Cavatak in a randomized study as either a monotherapy prior to surgery or in combination with other new immunotherapies is warranted,” Dr Andtbacka said.

Viralytics chief executive officer Dr Malcolm McColl said the company was “very pleased with the further excellent progress and latest results in the Calm trial, our rapid advance toward full enrolment and the strong support of international key opinion leaders to further assess Cavatak”.

“Our aim is to commence a randomized phase II trial in melanoma patients in the second half of 2014,” Dr McColl said.

Viralytics was up one cent or 2.9 percent to 36 cents.

IMMURON

Immuron says the US Food and Drug Administration has cleared its investigational new drug submission for a 60-patient phase II trial of IMM-124E for alcoholic steato-hepatitis.

Last year, Immuron said the trial had $US750,000 in US National Institutes of Health funding through the Richmond, Virginia-based Commonwealth University’s Prof Arun Sanyal and a consortium of the Commonwealth University, Mayo Clinic and Indiana University would perform the trial over a 30-day dosing regimen (BD: Aug 6, 2012).

Immuron chief executive officer Amos Meltzer told Biotech Daily that the three-arm trial would compare 1,880mg/day and 3,600mg/day doses of the bovine colostrum-derived therapeutic with controls.

Immuron said that for non-alcoholic steato-hepatitis (Nash) and alcoholic steato-hepatitis (Ash) had different causes, but both resulted in liver damage that could progress to liver fibrosis, liver cirrhosis and lead to of hepatic carcinoma.

The company said that the alcoholic steato-hepatitis trial was expected to provide it with additional guidance on its impending phase IIb non-alcoholic steato-hepatitis trials, which the FDA cleared last year (BD: Jan 22, 2012).

ANTEO DIAGNOSTICS

Anteo says it has an in-principle agreement with BBI Solutions to study the manufacturing and performance benefits of Mix&Go on BBI particles for lateral flow applications.
Anteo said the paid project built on previous work with the Cardiff, Wales-based BBI and would progress in agreed phases.
BBI said on its website that it was part of the Alere Group, formerly Inverness medical.
Anteo said the agreement was expected to lead to a commercial agreement on successful completion of the project.
BBI managing director Fiona Marshall said her company “has been interested in the benefits that may come from the use of Mix&Go in our systems for some time now”.
“Our earlier collaborative study has supported an assertion that Mix&Go may become part of our exciting portfolio of nano-particles,” Ms Marshall said.
Anteo chief executive officer Dr Geoff Cumming said the collaboration hoped “to play a part in ensuring their continued prominence in the global point-of-care diagnostics market”.
“This project is another step to achieving our objective of establishing Mix&Go as the preferred solution for binding proteins in diagnostics,” Dr Cumming said.
Anteo was up 0.2 cents or 2.8 percent to 7.4 cents with 23.6 million shares traded.

PATRYS

Patrys says it has been granted a second US patent for anti-cancer product PAT-LM1.
Patrys said that the patent entitled ‘Neoplasm specific antibodies and uses thereof’ was the second patent granted in the US and the third for the PAT-LM1 family.
The company said that in June, New Zealand granted a patent covering the use of the PAT-LM1 antibody or binding fragments for the treatment or prevention of metastasis.
Patrys said that the patent covered the PAT-LM1 antibody and other variants comprising the complementary determining region of the PAT-LM1 antibody.
Patrys chief executive officer Dr Marie Roskow said the patent expanded the intellectual property position and protects for PAT-LM1.
Patrys said it had related patents pending internationally and PAT-LM1 was in under preclinical development.
Patrys was up 0.6 cents or 12.8 percent to 5.3 cents with 158.5 million shares traded.

OSPREY MEDICAL

Osprey says it has completed its oversubscribed $14 million private placement of 21,538,461 CHESS depositary interests (CDIs) at 65 cents each.
Last month, Osprey said the funds strengthened its balance sheet as it prepared for the US launch of its Avert cardiac dye reduction system; completed the Avert trial to enhance the US Food and Drug Administration-approved marketing claim; completed a 20-patient diabetic limb recovery trial for Australian and European approval for the diabetic limb recovery product; further product development; and the launch of the Avert system targeted for mid-2015 (BD: Oct 16, 2013).
Osprey fell one cent or 1.4 percent to 72 cents.

BIODIEM

Biodiem has ended traded on the ASX and will be suspended from the close of trade tonight, November 8, 2013.
Biodiem originally listed on the ASX to develop a live attenuated influenza vaccine and BDM-E peptide for retinal eye disease and the antimicrobial BDM-I (BD: Jun 20, 2006).
Biodiem chief executive officer Tom Williams was succeeded by Dr Andrew O'Brien and Dr O'Brien was succeeded by Julie Phillips, who built a pipeline of products in development and collaboration with a number of institutes (BD: Feb 5, Jul 14, 2009).
The company has been tightly held with little liquidity.
Last year, the Bank of East Asia acting for David Li Kwok Po increased its substantial shareholding in Biodiem to 39,342,686 shares or 27.69 percent (BD: Dec 18, 2102).
The company's Appendix 4E Report said that chairman Hugh Morgan held 14,189,593 shares at June 30, 2013.
Biodiem closed up 0.1 cents or 2.6 percent to four cents.

BIOTRON

Nearly all Biotron shareholder votes opposed the re-election of director Bruce Hundertmark.
Mr Hundertmark faced 65,156,409 votes (97.4%) against his re-election, with 1,727,181 votes (3.6%) in favor.
Biotron's annual report and notice of meeting said that Mr Hundertmark was appointed a director on March 16, 2000.
The re-election of director Denis Wade and the adoption of the remuneration report were passed overwhelmingly.
Biotron was up 0.4 cents or 4.8 percent to 8.8 cents.

ALCHEMIA

Up to 10.7 percent of Alchemia shareholder votes opposed six resolutions providing 3,151,500 options to four directors, chief executive officer Charles Walker and former executive officer Dr Pete Smith.
The greatest dissent was against the issue to Mr Walker of 1,787,500 with 14,500,947 votes (10.7%) opposed to the resolution and 120,487,114 votes (89.3%) in favor.
The company's most recent Appendix 3B new issue announcement said that Alchemia had 324,338,515 shares on issue, meaning that the votes against Mr Walker's options amounted to 4.47 percent of the company, not the 5.0 percent required to requisition extraordinary general meetings.
Resolutions proposing to issue 191,000 options to each of directors Dr Tracie Ramsdale, Nathan Drona, Dr Susan Kelley and Tim Hughes and 600,000 options to Dr Smith were opposed by more than 10 million votes with more than 120 million votes in favor.
Resolutions on the adoption of the remuneration report, the approval of options and shares faced lower levels of dissent, with directors Dr Ramsdale, Mr Drona, Dr Kelley and Mr Hughes elected overwhelmingly.
Alchemia was up half a cent or 0.9 percent to 58.5 cents.

NANOSONICS

Nanosonics annual general meeting voted strong dissent against the re-election of chairman Maurie Stang as a director.
The re-election vote was opposed by 36,787,739 votes (23.6%), with 119.307,684 votes (76.4%) in favor.
The company's most recent Appendix 3B new issue announcement said that Nanosonics had 262,822,463 shares on issue, meaning that the votes against Mr Stang amounted to 14.0 percent of the company, sufficient to requisition extraordinary general meetings.
Former chief executive officer Dr Ron Weinberger was elected a director with 166,089,179 votes in favor and 6,599,185 votes against.
The Nanosonics share option plan also faced more than 5.3 million votes against but was passed easily with 166.5 million votes in favor, with all other resolutions passed overwhelmingly.
Nanosonics fell 2.5 cents or 2.9 percent to 85 cents.

PHOSPHAGENICS

Phosphagenics says an unnamed third party involved in its "invoice irregularities", the person's spouse and associated companies have entered into a deed of settlement.
In July, Phosphagenics said that about $5.7 million had been stolen and dismissed the then chief executive officer Dr Esra Ogru (BD: Jul 24, 2013).
Phosphagenics said at that time that it expected to recover "a substantial part of the misappropriated funds".
In August, Dr Ogru sold her shares in the company allowing it to recover $570,000 in what was described as "restitution".
Last week, Phosphagenics said that Dr Ogru, her husband and mother entered into a deed of settlement relating to stolen funds (BD: Oct 31, 2013).
Today, Phosphagenics said that under the deed with the unnamed third party and the third party's spouse and associated companies had taken responsibility for their involvement in the misappropriation and agreed to pay the company an amount equivalent to their full legal liability in respect of the misappropriated funds plus a fixed amount in respect of interest and costs.
The company said that the amount of funds it would recover would depend on the realizable value of the family assets.
Phosphagenics said that the deed of settlement was a better outcome than would have been achieved through court proceedings.
The company said that with the exception of the ongoing litigation against Robert Gianello and others, it had reached agreement with the parties involved in the misappropriation.
Phosphagenics was unchanged at 13.5 cents.