Biotech Daily

Wednesday November 5, 2008

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECHS DOWN: VENTRACOR UP 26.5%, BENITEC DOWN 16%**

*** VENTRACOR IMPLANTS 100th EURO PATIENT; CANNULA CE MARK**

*** MESOBLAST BEGINS PHASE I/II US BONE MARROW TRANSPLANT TRIAL**

*** PHOSPHAGENICS COMPLETES OBESITY TRIAL RECRUITMENT**

*** GBS CLOSES $100m BIOVENTURES IV FUND**

*** AUSTIN HEALTH JOINS BIONOMICS' PHASE I TUMOR TRIAL**

*** USCOM RELEASES OXYGEN MONITOR**

*** AVEXA PLEADS SCHULTZ TO ASX 70% SHARE PRICE QUERY**

*** C-BIO TO RAISE 'UP TO $10m'**

*** CAPITAL GROUP CLIENT TAKES 8.8% OF COCHLEAR**

MARKET REPORT

The Australian stock market climbed 2.8 percent on Wednesday November 5, 2008 with the All Ordinaries up 117.5 points to 4,287.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and nine were untraded.

Ventracor was best, up 2.2 cents or 26.51 percent to 10.5 cents with 2.06 million shares traded, followed by Avexa up 3.5 cents or 24.14 percent to 18 cents with 3.1 million shares traded.

Chemgenex climbed 13.21 percent, Bionomics was up 11.54 percent, Cytopia was up 8.57 percent, Phosphagenics and Universal Biosensors were up more than seven percent; Biota and Mesoblast were up five percent or more; with Prana and Sirtex up by more than two percent.

Benitec led the falls, down 0.8 cents or 16.0 percent to 4.2 cents, followed by Labtech down 15.15 percent to 14 cents and Peplin down 13.98 percent to 40 cents.

Phylogica lost 8.33 percent; Antisense was down 6.25 percent; Alchemia and Pharmaxis fell five percent; Novogen and Viralytics fell more than four percent; Arana was down 3.13 percent; Circadian, CSL, Polartechnics and Progen shed more than two percent; with Cochlear and Optiscan down more than one percent.

VENTRACOR

Ventracor says it has made “significant progress in the European commercialization of the Ventrassist left ventricular assist device (LVAD)”.

Ventracor said the 100th patient to receive a Ventrassist heart pump in Europe was implanted on October 29, 2008 at the Klinik für Thorax und Kardiovaskularchirurgie, Ruhr-Universität Bochum at Bad Oeynhausen in Germany by Prof Reiner Körfer .

The company said the 47-year old male patient with an idiopathic dilated cardiomyopathy, was making “an uneventful recovery”.

Ventracor chief executive officer Peter Crosby said Bad Oyenhausen was “one of the most prestigious hospitals implanting LVADs in the world and we are honoured that they have chosen Ventracor as a partner”.

Ventracor said it also had Conformitée Européenne (CE) Mark approval for a new family of in-flow cannulae, the tube that connects the heart to the pump.

The company said the first of the cannula family was pre-bent, more flexible and had a textured intra-ventricular section.

Ventracor said it was designed to give more options to surgeons when implanting the Ventrassist LVAD and recognized the principle “that one size does not fit all”.

The company said it intended to seek US Food and Drug Administration approval to introduce the new cannula into US clinical trials as soon as possible.

Ventracor said that after 413 days of support with the company’s cardiac pump, the heart of a 17 year old girl who had viral myocarditis had recovered.

The company said the surgery was performed by Dr Arnt Fiane from the Department of Cardiac Surgery under Professor Odd Geiran at the Rijkshopitalet in Oslo, Norway.

Dr Fiane said patients could recover after long term support by the Ventrassist LVAD.

He said he hoped to see more examples of cardiac recovery as the hospital’s experience grows.

Ventracor said the Rikshospitalet in Oslo had “further significant achievements” with a team jointly led by paediatric cardiac surgeon Dr Harald Lindberg and Dr Fiane implanting a Ventrassist LVAD into the smallest patient to date, a 10-year-old boy weighing 34kg.

The company said the boy was making “a good recovery and has returned to school just three weeks after the implant procedure”.

Ventracor said that Prof Hans H Scheld led a team at the Universitätsklinikum in Münster, about 50km north of Dortmund Germany, in their first implant of the Ventrassist device.

The company said the Münster group had “a long experience with mechanical circulatory support.

Prof Scheld said the group was “pleased to have moved on to using third generation devices and are impressed by the Ventrassist system so far”.

“Our first patient continues to recover even though he was very ill at the time of implant,” Prof Scheld said.

Ventracor said there were 27 implants of the Ventrassist left ventricular assist device worldwide during October.

With more than 370 patients implanted with the Ventrassist left ventricular assist device to date and 122 patients implanted in the US Bridge-To-Transplant clinical trial, Ventracor said there was more clinical experience with the Ventrassist left ventricular assist device “than with all other third generation centrifugal LVADs combined”.

Ventracor was up 2.2 cents or 26.51 percent to 10.5 cents.

MESOBLAST

Mesoblast has begun a phase I/II clinical trial in the US of up to 30 patients with haematologic malignancies undergoing bone marrow transplantation.

Mesoblast said the clinical trial will evaluate the safety and effectiveness of allogeneic or off-the-shelf mesenchymal precursor cells to increase the rate and speed of bone marrow engraftment following transplantation of haematopoietic stem and progenitor cells.

The company said the trial followed US Food and Drug Administration clearance of an investigational new drug submission and ethics approval by the institutional review board at the University of Texas MD Anderson Cancer Center in Houston.

The trial will be funded through a grant from the US National Institutes of Health.

The trial's principal investigator is Prof Elizabeth J Shpall.

Mesoblast said the mesenchymal precursor cells product used in the trial would be developed under the FDA orphan drug designation granted to Mesoblast's US-based sister company Angioblast Systems Inc for treating patients with haematologic malignancies requiring increased haematopoietic stem and progenitor cell production.

The company said orphan drug designation was for conditions affecting up to 200,000 patients a year in the US and allowed for an accelerated review process by the FDA, seven-year market exclusivity in the US on obtaining authorization, tax benefits and exemption from user fees.

For patients with haematologic malignancies, transplantation of haematopoietic stem and progenitor cells from the bone marrow of a healthy donor is a life-saving procedure as they rebuild bone marrow damaged and destroyed by cancer treatments, Mesoblast said.

About 30 percentof patients who could benefit from such a procedure have a genetically matched sibling and for the rest receiving a bone marrow transplant from an unrelated donor carries a high risk of potentially fatal graft-versus-host disease.

Mesoblast said umbilical cord blood was a preferred source of haematopoietic stem and progenitor cells because it has a reduced likelihood of causing graft-versus-host disease compared with bone marrow from an unrelated adult.

“However, the major limitation to cord blood use in adults is the limited number of haematopoietic stem and progenitor cells compared with bone marrow obtained from an adult,” the company said.

“This often results in delay or inability to achieve satisfactory bone marrow reconstitution, resulting in increased rate of graft failure, infections, bleeding and death,” Mesoblast said.

Mesoblast said Prof Shpall and her colleagues at the MD Anderson Cancer Center had been developing procedures for the ex-vivo expansion of cord blood for the past 10 years.

In a collaborative study with Angioblast, Prof Shpall showed that the proprietary allogeneic mesenchymal precursor cells (MPCs) could be used “to rapidly and significantly expand the number of haematopoietic progenitor cells present in cord blood”.

“The most promising results we have generated to date are with Angioblast's proprietary off-the-shelf MPCs,” Prof Shpall said.

“Haematopoietic progenitor cells present in cord blood can be expanded by over 20-fold following simple culture with the company's proprietary MPCs,” Prof Shpall said.

“Angioblast's off-the-shelf MPCs provide a very reproducible and standardized product for these gravely ill patients,” she said.

“As important, since time is critical in these procedures, these allogeneic MPCs are available for immediate use,” Prof Shpall said.

“We hope that these advantages will translate into faster and more effective bone marrow engraftment and improved patient outcomes,” she said.

Mesoblast climbed five cents or five percent to $1.05.

GBS VENTURE PARTNERS

GBS Venture Partners says it has closed its GBS Bioventures IV Fund with more than $100 million committed.

GBS said the 10-year fund had its first closing in March and had attracted commitments from funds advised by Macquarie Group, the Victorian Funds Management Corporation, Quay Partners, ARIA, the Meat Industry Employees' Superannuation Fund and Industry Funds Management. All had advised investors in other GBS funds.

Three investments have been made: Nuon Therapeutics, which is developing and commercializing therapies in inflammation and neurological disease; Elastagen Pty Ltd, which aims to commercialize work to isolate and manipulate recombinant human tropoelastin; and Peplin which is in a phase III trial of the clinical development of PEP005, a topical ingenol mebutate gel used to treat sun spots.

GBS said the close brought the total under management to more than $400 million.

GBS managing director Brigitte Smith said investors had faith in her company's track record.

"To get a commitment of more than $100 million in this very difficult investment climate is quite an achievement," Ms Smith said.

Ms Smith said it was also "a strong endorsement of Australasian life science".

"We believe that the current market creates an exceptional opportunity for a life science specialist to generate outstanding returns in the medium to long term," Ms Smith said.

"The fund will invest in companies that have a realistic opportunity to deliver a return to the fund in four to seven years through an Australian or international public offering or trade sale," she said.

"Investments will be in Australian and New Zealand companies, or US companies with substantial Australasian operations or technologies," Ms Smith said.

GBS is a private company.

BIONOMICS

Bionomics says Melbourne's Austin Health is the fourth clinical centre initiated for the final stage of the ongoing phase I clinical trial of anti-cancer drug BNC105.

Bionomics said the trial was being conducted under an investigational new drug application approved by the US Food and Drug Administration.

The company said that in January 2008, Cancer Trials Australia and Bionomics entered an agreement to conduct a first time in human study with BNC105.

The other sites are the Royal Melbourne Hospital, the Peter MacCallum Cancer Centre and the Western Hospital.

Bionomics chief executive officer Dr Deborah Rathjen said the BNC105 clinical trial was "progressing well through the dose escalation phase" with BNC105 demonstrating preliminary indications of biological effect as determined by dynamic contrast-enhanced magnetic resonance imaging and computed tomography scans.

"As the trial progresses … there will be a requirement to recruit greater numbers of patients to confirm the dose to be selected for phase II trials," Dr Rathjen said.

"It is important that this recruitment proceed as smoothly as possible and it is very pleasing to see Austin Health now part of the team to ensure that happens," she said.

Bionomics said BNC105 was a vascular disruption agent, which blocks the blood supply to a solid tumor, effectively starving the tumor of nutrients.

Separately, all motions to the company's annual general meeting were passed overwhelmingly, including all motions granting options to directors.

Bionomics climbed three cents or 11.54 percent to 29 cents.

PHOSPHAGENICS

Phosphagenics says recruitment of the Phospha E phase II clinical trial for the management of metabolic syndrome has been completed.
Five sites in Australia recruited a total of 160 patients for the efficacy trial.
Phosphagenics said that previously, two pre-clinical dose response trials confirmed that, when given orally, Phospha E "significantly reduced many of the key biomarkers associated with metabolic syndrome".
Phosphagenics said metabolic syndrome was characterized by a group of risk factors, that increase the threat of diabetes, coronary heart disease and other diseases associated with plaque build up in artery walls.
Several web-based definitions nominate obesity as the primary cause of the syndrome elevated blood pressure, cholesterol, triglycerides and blood glucose.
Phosphagenics said the phase II trial began late last year and was well advanced with the majority of patients nearing completion of the trial.
Phosphagenics said it expected to have the results from the trial before March 31, 2009.
The company said it had agreed on the principal terms of a commercialization agreement, which would grant a worldwide exclusive license to its partner, Nestlé, for the use of Phospha E in medical foods while maintaining its manufacturing base in Australia.
Under the terms of the agreement, Phosphagenics would be the exclusive manufacturer and supplier of Phospha E.
The decision whether to execute a final commercial agreement will be made once the results of the phase II trial have been assessed, the company said.
Phosphagenics' chief executive officer Harry Rosen said the American Heart Association estimated that more than 50 million Americans had metabolic syndrome.
"We believe that commercial demand for medical foods containing Phospha E, if it is approved, could be considerable," Mr Rosen said.
Phosphagenics was up half a cent or 7.14 percent to 7.5 cents.

USCOM

Uscom says it has released its new cardiovascular product, Oxycom.
Uscom said Oxycom was a patent protected device based on the Uscom 1A technology, which provides unique non-invasive measures of oxygen delivery and was first presented at the Australian and New Zealand Intensive Care Society annual meeting in Sydney on October 30, 2008.
The company said Oxycom was the second in the planned Uscom product pipeline based on patent protected concepts to improve cardiovascular measurement and care.
Uscom said that previously oxygen delivery has been measured using invasive catheters to sample blood from within the heart and results often took over an hour to return.
There are also pulse oximeters that clip onto a fingertip giving blood axygen saturation readings.
Uscom said Oxycom provided the same information as catheter measurement instantaneously and non-invasively and could be used on small children through to geriatrics.
Uscom executive chairman Rob Phillips said oxygen consumption was "a critical measure of circulation and one which can be used to guide treatment in many diseases".
"It is a real 'holy grail' measurement for clinicians and we can now provide it non-invasively so it can be included as a routine part of practice," Mr Phillips said.
Uscom was up three cents or 10.34 percent 32 cents.

AVEXA

Avexa has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose from 11.5 cents on October 31, 2008 to 19.5 cents today, along with an increase in trading volume.
Avexa's chief executive officer Dr Julian Chick and chief scientific officer Dr Jonathan Coates have been in Europe and the US where they attended meetings including potential fund raising.
Today both executives were in Sydney with chief financial officer Alan Boyd.
No one from Avexa was available to comment.
Avexa closed up 3.5 cents or 24.14 percent at 18 cents with 3.1 million shares traded.

C-BIO

C-Bio hopes to raise an initial $3.9 million through a one-for-10 shares offer of 3,940,543 shares at $1 a share.
"This offer is the first stage of a funding round under which the directors' currently intend to target raising an aggregate of up to $10 million," C-Bio said in a media release.
The public unlisted company said the funds would go to working capital needs to further progress the 150 patient rheumatoid arthritis clinical trial of its lead product Xtoll or Chaperonin 10 (CPN10), "a heat shock protein" being run in collaboration with the Denmark-based Novo Nordisk.
The record date for eligible shareholders is November 7, 2008.
The offer opens on November 7, 2008 and closes on November 28.
C-Bio said the funds were for working capital and to "provide a future opportunity to raise new proceeds of up to $10.6 million, if the options are exercised".
The rights offer is not underwritten and the shortfall if any can be issued to people who are not currently shareholder.
C-Bio has 39,405,439 shares on offer, with 979 individual shareholders
Separately, C-Bio has asked shareholders to consider the issue of 1,000,000 options exercisable at $1 each to director Dr Michael Monsour.
The annual general meeting will be held at BTP Technology and Conference Centre, Brisbane Technology Park, 1 Clunies Ross Court, Eight Mile Plains, Queensland on November 25, 2008.
C-Bio is a public unlisted company.

COCHLEAR

The US based Capital Group Companies has increase its substantial shareholder in Cochlear from 4,328,856 (7.75%) to 4,927,063 shares (8.82%) on November 3, 2008.
The Capital Group said it did not own shares in Cochlear but held them on account for an unnamed client.
Cochlear fell 97 cents or 1.64 percent to $58.03.