Biotech Daily

Wednesday October 27, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP:**
- CLINUVEL, SUNSHINE HEART UP 11%; PATRYS DOWN 7%

*** LIVING CELL: 10 DIABETES PATIENTS IMPLANTED; DOSE QUESTIONS**

*** WEHI'S DR CLARE SCOTT WINS $400k OVARIAN CANCER FELLOWSHIP**

*** IMMURON'S IMM255 INHIBITS 'FLU VIRUS IN MICE**

*** CELLMID'S ADVANGEN TO DEVELOP MIDKINE HAIR-LOSS TREATMENT**

*** AGENIX, BIOTRON VOTE ON DIRECTOR SHARES**

*** ANTISENSE REQUESTS CAPITAL RAISING TRADING HALT**

*** STEPHEN CARTER REPLACES EASTLAND CEO DERMOT PATTERSON**

*** GIACONDA HAS VERY LITTLE CASH**

*** MEDIATION ENDS BIOPROSPECT, SOLAGRAN DISPUTE**

MARKET REPORT

The Australian stock market fell 0.85 percent on Wednesday October 27, 2010 with the S&P ASX 200 down 39.7 points to 4648.1 points. Fifteen of the Biotech Daily Top 40 were up, 10 fell, 11 traded unchanged and four were untraded.

Clinuvel and Sunshine Heart were best, up 11.1 percent to 20 cents and three cents, respectively, with 203,000 shares and 110,000 shares traded, respectively.

LBT and Mesoblast climbed more than six percent; Phosphagenics, Phylogica and Resmed were up four percent or more; Circadian, Impedimed and Viralytics were up more than three percent; Heartware, QRX and Starpharma rose more than two percent; with Acrux, Biota and Sirtex up more than one percent.

Partys led the falls, down 0.7 cents or 8.2 percent to 7.8 cents with 281,533 shares traded, followed by Benitec down 5.7 percent to 3.3 cents with 2.1 million shares traded.

Genera fell four percent; Prana and Prima lost more than three percent; Cochlear shed 2.3 percent; with Cellestis, Pharmaxis, Tissue Therapies and Universal Biosensors down more than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says 10 of 12 insulin-dependent diabetes patients in its phase II trial have received implants of encapsulated porcine islets of Langerhans.

Living Cell the New Zealand trial was continuing to achieve positive results.

The company said the first group of four patients received one implant of Diabecell at the dose of 10,000 islet equivalents per kilogram body weight (IEQ/kg).

Living Cell said one patient from this group had been followed-up for 52 weeks and the other three patients for a minimum of 30 weeks.

In all patients in this group there has been a reduction in the number and severity of hypoglycaemic events, episodes when blood glucose levels were very low and may lead to loss of consciousness and convulsions without warning symptoms, the company said.

The average decrease in the severity of low blood glucose events at 24 weeks in this group was “a remarkable 64 percent” the company said.

Living Cell said that more compelling was the reduction in life-threatening unaware low blood glucose events, which dropped by an average of 76 percent with one patient, followed-up for 52 weeks, had not had a single unaware event since week five and that change “significantly improved his quality of life and relieved family stress”.

Living Cell said that by week 24, patients in the first group had reduced their insulin dose by an average of 32 percent. The daily insulin dose is adjusted according to daily blood glucose measurements by the patient.

Details of blood glucose monitoring were blinded to the clinical team who were serving as independent trial officiators and would be unblinded after one year of follow-up.

Living Cell said there had been no reported product-related adverse events.

Living Cell’s medical director Prof Bob Elliott said “the initial beneficial results of Diabecell are being sustained and are having a dramatic positive impact on the lives of implant recipients and their families”.

“Hypoglycaemic unawareness is a dangerous complication which occurs in about 20 percent of insulin dependent diabetic people and is responsible for up to eight percent of deaths in this group,” Prof Elliott said.

“The ability to reduce the likelihood of these dangerous events is a significant step toward normalizing the lives of our patients,” Prof Elliott said.

Living Cell said the second group of four patients had received a dose of 15,000 IEQ/kg with no significant adverse events attributed to the treatment.

The company said the patients had been followed-up for more than 12 weeks and had shown an average reduction in the severity of low blood glucose events of eight percent and a significant reduction in unaware low blood glucose events of 30 percent.

Living Cell said that the fact that the hypoglycaemic episodes had not reduced at a greater rate compared with patients treated at the lower level dose of 10,000 islet equivalents per kilogram body weight (IEQ/kg) provided “important information to determine the ideal dose range for patients and is a key component of this trial as the company moves closer to identifying its target product profile”.

In the third group of four patients, two have received a higher dose of 20,000 IEQ/kg with no significant adverse events attributed to the treatment, but Living Cell said the follow-up period was too short to assess response to treatment.

Living Cell chief executive officer Dr Ross Macdonald said the company expected the dose seeking studies to continue delivering positive results and important information.

“With consistent benefit in the form of reduction or elimination of hypoglycaemic events, [the company] is planning to expand clinical trials of Diabecell to obtain the necessary pivotal data for the treatment to be approved,” Dr Macdonald said.

Living Cell was unchanged at 16.5 cents.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says Dr Clare Scott has won a $400,000 two-year Victorian Cancer Agency clinical fellowship for research into ovarian cancer.

The Institute said epithelial ovarian cancer was found in the cell lining of the ovary and accounted for 90 percent of ovarian tumors, but epithelial ovarian cancer was poorly understood and recent research shows that it might start in cells outside of the ovary.

The Institute said Dr Scott was a laboratory head in its stem cells and cancer and molecular genetics of cancer divisions and an oncologist at the Royal Melbourne Hospital.

Dr Scott said the fellowship would help her search for the origins of ovarian cancer.

"In addition to working out where ovarian cancer starts, we need more precise ways of studying human ovarian cancers in the laboratory and, with the VCA funding, we will work on improving those laboratory models," Dr Scott said.

The Institute said that more than 1200 Australian women were diagnosed with ovarian cancer each year and about 800 would die from the disease.

IMMURON

Immuron says its bovine colostrum based product for influenza IMM255 has shown "high haemagglutination inhibitory and virus neutralizing actions" in mice.

Immuron said that a single administration of IMM255 prevented the establishment of infection with a sub-lethal dose of influenza A/Puerto Rico/8/34 (PR8) virus when given as early as seven days prior to exposure to virus.

The company said the preclinical data, published on line in the Public Library of Science (Plos One), said pre-treated mice also survived an otherwise lethal dose of virus.

Immuron said that the successful reduction of established infection with the highly virulent virus was also observed using a single treatment 24 hours after virus exposure.

Immuron said the study showed that IMM255 could be a valuable addition to, or substitute for, antiviral drugs and vaccines to control influenza with the advantage of eliminating the need for daily administration.

The article, entitled 'Prevention and Treatment of Influenza with Hyperimmune Bovine Colostrum Antibody' is available at http://dx.plos.org/10.1371/journal.pone.0013622.

Immuron said hyper-immune bovine colostrum, from cows vaccinated with PR8 influenza virus was shown to have high haemagglutination inhibitory and virus neutralizing actions.

The company said that in mice, a number of influenza-targeting antiviral drugs were experiencing issues with resistance as the influenza strains change.

Immuron said that its polyclonal antibody approach was unlikely to suffer from this problem on the basis that while its polyclonal antibodies provided broad protection, they had less effect in driving the selection of resistance.

The company said IMM255 was expected to have an increased lifespan for use against naturally occurring viral drift variants due to neutralizing antibodies against viral strains that persist for several years.

Immuron said the polyclonal antibody approach used with IMM255 might have a significant role in reducing morbidity and mortality in the population who had either not been vaccinated or those who have been vaccinated but failed to seroconvert such as the elderly or those with compromised immune systems.

Immuron chief executive officer and co-author of the report Dr Grant Rawlin said the company was "delighted to see this study published".

"Work continues to progress well with our ferret influenza trials, which we hope will form the basis for our progress into the clinic with this product candidate," Dr Rawlin said.

Immuron was unchanged at 7.9 cents.

CELLMID

Cellmid says it has created a wholly-owned subsidiary Advangen International to develop midkine-based cosmetics, beginning with a hair loss treatment.

Cellmid chief executive officer Maria Halasz told Biotech Daily that Advangen International would distribute an alternative hair loss treatment developed by Japan's Advangen Inc in Australasia, Europe and the US and had adopted the name of the Japanese company.

Cellmid said the market for hair loss products was estimated to be several billion dollars a year, with most spent on products with little or no scientific basis.

Cellmid said Advangen would develop over-the-counter pharmacy products "subject to the strict ethical product development standards of its parent company".

The company said that Advangen had filed a provisional patent application and would conduct pre-clinical safety and efficacy trials and subject to preclinical validation it would validate midkine for the treatment of various forms of alopecia in humans in controlled clinical trials.

Cellmid said that to facilitate the funding of the subsidiary it had negotiated exclusive Australasian distribution rights to a range of market-ready, scientifically-validated hair growth products from Japan's Advangen Inc including hair growth shampoo, scalp lotion for women and scalp lotion for men.

Cellmid said the products had been sold in Japan with more than 500,000 units of scalp lotion sold during the first two years of marketing.

Cellmid said the Japan's Advangen developed the products and one of the key active ingredients, Sanguisorba officinalis root, was shown to inhibit FGF-5, a protein that triggers a transition in hair cycle and eventual hair loss.

Cellmid said that animal and human studies demonstrated that using this FGF-5 inhibitor decreased the amount of hair lost and extended the growth phase (anagen) of each hair follicle, which over time, should result in a fuller head of hair, with increased hair thickness and length.

Ms Halasz said Sanguisorba officinalis root was not related to her company's midkine assets.

Ms Halasz said her Advangen International would distribute the Japanese products as well as develop a midkine product for hair loss.

Ms Halasz said the products were developed to ethical pharmaceutical standards and the active ingredient was registered by Japan's Ministry of Health and Welfare.

Cellmid said Advangen would be funded by a loan from Cellmid and subject to initial test marketing the subsidiary was expected to generate the majority of its revenue from product sales.

Cellmid said its staff would run Advangen with all sales and marketing functions contracted to third party specialist organizations.

Cellmid was unchanged at 2.1 cents with 4.3 million shares traded.

BIOTRON

Biotron shareholders will vote on the grant of 5,000,000 options to chief executive officer Dr Michelle Miller.

The options are exercisable at a range of prices expiring on October 30, 2015.

The meeting will also vote on the election of directors Michael Hirshorn and Denis Wade.

The meeting will be held at Biotron, Level 3, 66 Hunter Street, Sydney, on November 26, 2010 at 11am (AEDT).

Biotron was untraded at 9.4 cents.

AGENIX

Agenix shareholders will vote on the grant of 10,000,000 options to chairman Nicholas Weston and 10,000,000 shares to director John Tong.
Agenix will also vote on the issue of 3,000,000 rights each to directors Christopher McNamara and Anthony Lee.
The meeting will also vote on the employee option plan, the director and executive equity plan and the re-election of Mr Lee.
The meeting will be held at the William Buck boardroom, Level 1, 465 Auburn Road, Hawthorn East, Melbourne on November 26, 2010 at 10am (AEDT).
Agenix was up 0.2 cents or 10 percent to 2.2 cents.

ANTISENSE THERAPEUTICS

Antisense has requested a trading halt pending an announcement on a capital raising.
Trading will resume on November 1, 2010 or on an earlier announcement.
Antisense last traded at 1.4 cents.

EASTLAND MEDICAL SYSTEMS

Eastland has appointed Stephen Carter as chief executive officer and a director, replacing Dermot Patterson.
Eastland said Mr Carter had extensive pharmaceutical industry experience and had held senior positions with listed public companies including as chairman and managing director.
The company said Mr Carter had extensive contacts and experience in the financial markets and the pharmaceutical industry and was well-equipped to lead executive management through the commercialization phase of the project.
Eastland said Mr Patterson would assist the company in an orderly transition.
Eastland paid significant tribute to Mr Patterson's efforts for the company.
"Shareholders may never fully understand the extent of the contribution made by Mr Patterson and are fortunate to have both access to and the ongoing support of Mr Patterson during this transition," Eastland said.
Eastland said that non–executive chairman Peter Jooste would "guide and support a process that will lead to the appointment of a new chair with appropriate industry and connected financial market experience".
Once a new chair was appointed Mr Jooste would become a non-executive director.
Eastland said it had begun a four-country phase III trial which was expected to provide the clinical data necessary to support a submission for regulatory marketing approval.
The company said that dosing in Rwanda was expected to begin in late October 2010.
Eastland fell 0.2 cents or 3.2 percent to six cents with 3.1 million shares traded.

GIACONDA

Giaconda says its net operating cash burn for the three months to September 30, 2010 was $358,000 with cash at the end of the quarter of $94,000.
Giaconda provided no further information.
Giaconda last traded at 3.2 cents.

BIOPROSPECT, SOLAGRAN

Bioprospect says it has withdrawn its court case against Solagran after mediation in Melbourne and Solagran has withdrawn its cross-claim.

Bioprospect said the parties agreed that the development agreement of August 22, 2007 had been terminated and would pursue their business strategies separately.

The two companies have been in dispute for several months (BD: Jun28, Jul 29, Aug 5, 2010).

Bioprospect said its development work would no longer be based on Solagran's Bioeffective A product and would instead use a different raw material, coniferous chlorophyll-carotene paste.

Bioprospect was up 0.2 cents or 18.2 percent to 1.3 cents.

Solagran was up half a cent or four percent to 13 cents.