Biotech Daily

Thursday March 3, 2011

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: CELLMID UP 10%; LIVING CELL DOWN 7%**

*** QUESTIONS RAISED ON ATEC; NEOPEC SAFE**

*** FEDERAL GOVERNMENT REPORT 'BOOSTS CLINICAL TRIALS EFFORTS'**

*** CALZADA'S POLYNOVO COMPLETES ANIMAL BURNS TRIAL**

*** CLINUVEL READY FOR SCENESSE TRIAL FOR VITILIGO**

*** STARPHARMA WINS $250k VICTORIA AGRICULTURE DENDRIMER GRANT**

*** PHOSPHAGENICS PARTNERS ON BOVINE MASTITIS**

*** GIACONDA ADMINISTRATORS APPOINTED**

*** FABIO PANNUTI TAKES 7.4% OF HELICON**

*** EU GRANTS AGENIX ANTIBODY PATENT**

MARKET REPORT

The Australian stock market edged up 0.07 percent on Thursday March 3, 2011 with the S&P ASX 200 up 3.2 points to 4806.4 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, six traded unchanged and seven were untraded.

Cellmid was best, up 0.3 cents or 10.3 percent to 3.2 cents, with 1.0 million shares traded.

Genetic Technologies climbed 7.95 percent; Tissue Therapies was up 6.9 percent; Bionomics, Cathrx and Mesoblast were up five percent or more; Phosphagenics and Viralytics both climbed 4.35 percent; Sirtex and Starpharma were up three percent or more; Acrux and Universal Biosensors rose more than two percent; with Chemgenex, Clinuvel, CSL and Resmed up one percent or more.

Living Cell Heart led the falls, down 0.7 cents or 6.7 percent to 9.8 cents, with 1.1 million shares traded.

Prana lost 3.3 percent; Prima shed 2.1 percent; with Cellestis, Heartware Phylogica and QRX down more than one percent.

AUSTRALIAN TISSUE ENGINEERING CENTRE, NEOPEC

Several separate sources have told Biotech Daily that there have been questions raised about the future of the Australian Tissue Engineering Centre (ATEC).

ATEC was established in 2007 with a Victorian Government $5.2 million grant to integrate research institutions including the Bernard O'Brien Institute of Microsurgery, the Australian Stem Cell Centre, the University of Melbourne and St Vincent's Hospital (BD: Mar 28, 2007).

In 2009, the Victoria Government provided $2.95 million to ATEC to develop the Neopec technology (BD: Oct 29, 2009). ATEC is related to the Bernard O'Brien Institute and both are based at St Vincent's Hospital.

ATEC is a sponsor of Neopec, which was created to develop a technique for women to regrow pectoral muscle tissue following mastectomy (BD: Apr 16, 2010).

Neopec said last year that the technique was developed by scientists at the Bernard O'Brien Institute and the process implanted a biodegradable synthetic chamber and using the breast cancer patient's own regenerative capacity built a breast that looked and felt like her other breast. Trials are underway.

A spokesman for St Vincent's Hospital has told Biotech Daily that the future of Neopec was secure.

"I can 100 percent guarantee that Neopec is not under threat," the spokesman said.

He said the Neopec project was progressing and an update would be released in due course.

Through the spokesman, Bernard O'Brien director Prof Wayne Morrison said: "The O'Brien Institute is in the process of streamlining operations".

"This involves discussions with ATEC," Prof Morrison said. "There is no impact on the research program."

There was no one available at ATEC.

In November last year, ATEC said it was establishing "a major biotechnology centre in Bahrain" (BD: Nov 15, 2010).

FEDERAL GOVERNMENT

The Federal Government says it has accepted the recommendations of the Clinical Trials Action Group report.

A statement by the Minister for Health and Ageing Nicola Roxon and Innovation Minister Senator Kim Carr said the changes recommend in the report would "boost pharmaceutical research and development and improve the clinical trials approval process".

Senator Carr said the microeconomic reform would improve productivity and have benefits for patients, industry, researchers and government.

"The new policies that will stem from this report will ensure Australia remains internationally competitive in clinical trials," Senator Carr said.

The Government media release said the report recommended how to make approval processes for clinical trials being conducted in different states and territories more efficient; increase the benefits to the health system that come from electronic communications reforms; and encourage more people to be involved in clinical trials.

Senator Carr said the estimated the annual economic worth of clinical trials to be in the order of $450 million. He said trials provided high-skill, high-wage jobs for Australians.

The Australian Government's Chief Medical Officer, Professor Jim Bishop, was a member of the Clinical Trials Action Group and chaired one of the expert reference groups.

Professor Bishop said that about 50 people were involved in the expert reference groups including clinicians, researchers, companies and government officials.

The report can be found under Ministerial News at http://www.innovation.gov.au

CALZADA, POLYNOVO BIOMATERIALS

Calzada says a pre-clinical trial has shown its Novoskin bioresorbable temporizing matrix is superior to a collagen-based “current leading dermal replacement product”.

Calzada said the trial of Novoskin bioresorbable temporizing matrix (BTM) in pigs by its wholly-owned subsidiary, Polynovo Biomaterials showed 23.44 percent wound contraction compared to the collagen product’s 55.56 percent.

Calzada chief executive officer Dr Stewart Washer said that wound contraction needed to be avoided to ensure complete healingmatrix or shrinking was a disbenifit as

“The less it shrinks back, the better healing you get,” Dr Washer said.

Calzada said that the collagen-based treatment had a 66.67 percent major infection rate compared to Novoskin’s zero rate for major infections.

Polynovo chief executive officer Laurent Fossaert said the results were very encouraging.

“These efficacy benefits, combined with the significantly lower cost of manufacture and greater product robustness of BTM provide us with the necessary results to now progress to complete required safety studies and then move to a pilot human trial for the device later this calendar year,” Mr Fossaert said.

Calzada said the final animal study was performed by Polynovo 80 percent subsidiary, Novoskin, a joint venture with Skin Pty Ltd a company related the Royal Adelaide Hospital burns unit director Prof Dr John Greenwood.

Calzada said the Novoskin BTM was tested against the commercial product for full thickness burns in six pigs, repairing 8cm by 8cm full-thickness surgical wounds.

The company said the device was used in major burn practice to physiologically close the wound reducing contraction and preparing the wound bed for later skin grafting.

Calzada said the data showed clear evidence of superior efficacy including less infection and less contraction in an animal model which was directly relevant for the clinical application and would be used to prepare Novoskin’s human research ethics committee submission for a human clinical trial.

The company said Novoskin was developing a product suite for the treatment of third degree burns with the bioresorbable temporizing matrix designed to allow dermal tissue to grow within it while stabilizing the patient until skin grafts are available.

Calzada said the second Novoskin product was the cultured composite skin in which a small biopsy was taken from the patient and skin sheets were manufactured using Novosorb scaffolds and the patient’s own cells.

Prof Greenwood said the prominence of collagen for dermal scaffolds was waning.

“Materials of this origin are expensive to produce and regulate and limited in their properties,” Prof Greenwood said.“Novoskin’s completely synthetic dermal template appears extremely robust to infection, which frequently results in loss of commercial alternatives,” Prof Greenwood said.

“Since these materials are fundamental to survival in burns of greater than 50 percent of the body, loss through infection frequently has mortal consequences,” he said.

“That the BTM resulted in highly significant preservation of wound size, [or] less contraction, will ensure better functional results for patients and subsequently less need for reconstructive surgery,” Prof Greenwood said.

“This product appears to successfully fulfil the first stage of our planned two-stage strategy to abolish the skin graft,” Prof Greenwood said. “In the interim the BTM, in different structural forms, has the potential to replace market leaders in dermal replacement in a range of indications.”

Calzada said studies underway to test the polymer safety were due for completion in December 2011 in preparation for a submission for clinical trials in burns patients.

Calzada was up 0.1 cents or 1.33 percent 7.6 cents with to 4.55 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says the US Food and Drug Administration has approved a pilot phase II clinical trial of afamelanotide in patients with non-segmental vitiligo.

Clinuvel said the FDA had allowed the trial under the existing investigational new drug application.

The company said it would be the first time afamelanotide (to be marketed as Scenesse) would be tested as a repigmentation therapy in non-segmental vitiligo, a disorder affecting more than 45 million individuals globally.

Clinuvel said that vitiligo was a disease causing white or off-white depigmented skin lesions to appear on different parts of the body due to a loss of melanin production and could spread over time and cause patients significant psychological and emotional distress.

The company said the exact cause of vitiligo was unknown, but it was generally recognized that an autoimmune component plays a role in the disease.

Clinuvel said the trial, designated CUV101, was a multi-centre, six-month, open-label, pilot study to evaluate the efficacy of Scenesse as a combination therapy with narrowband ultraviolet B (NB-UVB) phototherapy compared to NB-UVB alone.

The company said the goal of the trial was to determine whether Scenesse would reduce the total dose of radiation (NB-UVB) and the time required to reactivate skin pigment producing cells in vitiliginous lesions.

Clinuvel said narrowband ultraviolet B phototherapy clinically administered three times a week over 18 months was considered the standard of care in non-segmental vitiligo to prevent the progression of lesions and stimulate repigmentation in depigmented skin.

The company said Scenesse would be administered every 28 days to 50 percent of the trial patients.

Clinuvel said all trial patients would be treated with narrowband ultraviolet B phototherapy three times a week for six months for a total of 72 treatments total and repigmentation and maintenance of pigmentation would be evaluated using the internationally recognized vitiligo area scoring index (VASI) and vitiligo European task force (VETF) evaluation system and overall results would be compared.

The company said the trial would be conducted in six centres, California, Michigan, New York, France, Italy and Switzerland – with each centre recruiting up to 20 patients, starting in the US later this month.

Clinuvel said the Italian regulatory agency had approved the study and submissions have been made to the Swiss and French regulatory agencies.

Clinuvel's chief scientific officer Dr Hank Agersborg said it was "an historic trial in dermatology, as there has really not been an effective therapy for these patients".

"For Clinuvel it is the first time we will administer Scenesse to treat a disease rather than as prophylaxis," Dr Agersborg said.

"The combination therapy with narrow-band UVB is very promising," Dr Agersborg said.

"Vitiligo is an exciting new therapeutic area for Clinuvel and one which we prepared for years with the selected centres of excellence," Dr Agersborg said.

"From a biochemical point of view, the use of Scenesse makes much sense. Narrowband UVB induces melanocortin-1 receptor status in differentiating pigmentary stem cells at deep levels of the skin. Subsequent administration of Scenesse should aid the pigment cells to produce pigmentation by restarting the cellular machinery," Dr Agersborg said.

Clinuvel said further trial details were on its website: http://www.clinuvel.com/vitiligo.

Clinuvel was up two cents or one percent to $2.05.

VICTORIAN GOVERNMENT, STARPHARMA HOLDINGS

Starpharma says the Victorian Government has awarded it $250,000 to further develop its Priostar dendrimer agricultural program.

Starpharma said the funding was announced by the Minister of Technology, Gordon Rich-Phillips, as part of the Victorian Government's Small Technologies Industry Uptake Program.

The company said the Priostar dendrimer technology was hoped to improve delivery of agricultural chemicals to enable healthier plant growth and fight plant disease.

Starpharma chief executive officer Dr Jackie Fairley told Biotech Daily that by adding the dendrimer nano-particles to batches of agrochemicals they improved water solubility of the chemicals, meaning that less water needed to be added to the active ingredient, for the same plant uptake.

Dr Fairley said the dendrimers provided greater chemical adhesion to plant material and extended the effect and the dendrimers also reduced the ultra-violet light degradation of the active chemicals.

Starpharma said that as well as increasing efficacy, improved delivery control of chemicals could reduce both the frequency of application and amount applied with the potential to reduce farmers' costs and the environmental impact of agricultural chemicals.

Starpharma said the Priostar dendrimers had shown “valuable properties for agrochemicals in previous studies” and the company was working with agricultural chemical companies to advance several projects.

The company said the Victorian Government funding would allow it to independently undertake further agricultural trial work using specialist organizations.

Starpharma chief executive officer Dr Jackie Fairley said the funding would allow her company “to generate important additional data on several generic agrochemical agents in our own trials”.

“Successful completion of these trials will represent an important advance in the development of this valuable technology and will further enhance its commercial value,” Dr Fairley said.

Starpharma said the global market for agricultural chemicals in 2008 was estimated at $US35.8 billion and comprised insecticides, herbicides and fungicides, all of which were amenable to improvement by its Priostar dendrimers, a type of precisely-defined, branched nanoparticle.

Starpharma said the technical approach to agricultural applications was an extension of Starpharma's drug delivery program, in which dendrimers advantageously modify the properties of drug molecules and were originally developed by Starpharma's US subsidiary DNT Inc.

Victoria’s Minister for Technology Gordon Rich-Phillips said Global Kinetics Corp had also been awarded funds from the program to develop a micro-electro-mechanical system for the treatment of patients with Parkinson’s disease along with Adalta to identify and manufacture nano-scale antibodies to reduce drug discovery timelines.

“Bringing together Victoria’s capabilities in micro and nano-technology with our strengths in biotechnology, ICT, smart engineering and medical manufacturing will deliver substantial economic benefits, to Victoria and beyond,” Mr Rich-Phillips said.

A State Government media release said the Small Technologies Industry Uptake Program used a system of vouchers to support Victorian businesses to adopt small technologies, such as micro-electronics and nano-technology, with vouchers exchanged for access to small technologies facilities, services, advice or expertise provided by approved suppliers.

Starpharma was up four cents or 3.7 percent to $1.13 with 2.7 million shares traded.

PHOSPHAGENICS

Phosphagenics says it has partnered with dairy research company Mastitis Management Australia to use its technology for bovine mastitis.
Phosphagenics said its tocopheryl phosphate mixture or TPM delivery technology would deliver a natural formula targeting mastitis, or blocked milk ducts, in dairy cows, which cost world farmers $54 billion a annum.
The company said that independent dosing trials determined the formula coupled with Phosphagenics' technology was able to lower the somatic cell count (white blood cells) in diseased cows, a key indicator of infection, by up to 90 percent in four weeks.
The company said Mastitis Management Australia would licence the technology in Australia and New Zealand and with a combined herd of six million cows meant about 900,000 had clinical and sub-clinical mastitis.
The company said the product would be delivered to cows via a drench and was expected to be launched in the second half of this year.
Phosphagenics said the treatment contained vitamins and could be an alternative to antibiotic therapy, which was expensive and contributed to antibiotic resistance as well as antibiotic treatment leading to withholding milking, which cost the industry.
Phosphagenics chief executive officer Dr Esra Ogru said the partnership was "an example of the versatility of the company's proprietary platform TPM delivery technology".
Phosphagenics was up half a cent or 4.35 percent top 12 cents.

GIACONDA

Crouch Amirbeaggi Insolvency Accountants say that Nicholas Crouch has been appointed the administrator of Giaconda.
Crouch Amirbeaggi said the first creditors meeting would be held at Suite 403, 55 Lime Street, King Street Wharf, Sydney on March 9, 2011 at 2pm (AEDT).
The company said shareholders were not invited to the creditors meeting and a shareholders agreement would be held on or about April 15, 2011.
Giaconda last traded at 3.4 cents.

HELICON GROUP

Fabio Pannuti has become a substantial shareholder in Helicon with the acquisition of 36,859,135 shares or 7.41 percent of the company.
The initial substantial shareholder notice said the holdings were held by Inverness Group and Ecosse Equities and the consideration was 19,926,016 Leading Edge shares.
Helicon fell 0.2 cents or4.4 percent to 4.3 cents.

AGENIX

Agenix says it has been granted a European Union patent for 'Humanised antibodies derived from DD-3B6/22, specific for the D-Dimer fragment of Fibrin'.
Agenix said the patent referred to the basis of the company's Thromboview diagnostic.
Agenix executive chairman, Nick Weston said the patent was "a significant milestone because the European Union is a crucial market for extracting value from Thromboview".
Agenix was up 0.4 cents or 18.2 percent to 2.6 cents with 1.4 million shares traded.