Biotech Daily

Wednesday November 3, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: CELLMID UP 216%; BENITEC DOWN 13%**

*** CELLMID, BIOGENES DEVELOP MIDKINE ELISA TEST FOR CANCER**

*** AUSTRALIAN RESEARCH COUNCIL 'STREAMLINED' GRANTS PAPER**

*** VIRALYTICS ASKS FDA FOR HIGHER DOSE CAVATAK MELANOMA TRIAL**

*** IMMURON DETAILS LIVER DISEASE HUMAN, MOUSE DATA**

*** BROADVECTOR APPOINTS ALPHA, EXTENDS IPO**

*** ELLEX SEALS 2nd CENTREVUE DISTRIBUTION DEAL**

*** NOVOGEN APPOINTS PETER SCUTT DIRECTOR**

*** AGENIX APPOINTS DR DANYI ZHANG THROMBOVIEW CHAMPION**

MARKET REPORT

The Australian stock market was up 0.45 percent on Wednesday November 3, 2010 with the S&P ASX 200 up 21.2 points to 4722.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and six were untraded. All three Big Caps were up.

Cellmid was best, up 4.1 cents or 215.8 percent to six cents with 377.6 million shares traded, followed by Living Cell up 13.3 percent to 17 cents with 272,723 shares traded.

Compumedics and Patrys climbed four percent or more; Sunshine Heart and Viralytics were up more than three percent; Optiscan rose 2.4 percent; with Acrux, Cellestis, Cochlear, CSL, Immuron, Impedimed, Nanosonics, Resmed and Starpharma up more than one percent.

Benitec led the falls, down 0.5 cents or 12.8 percent to 3.4 cents with 1.7 million shares traded, followed by Clinuvel down 5.3 percent to 18 cents with 67,500 shares traded.

Phosphagenics lost four percent; Bionomics fell 3.8 percent; Uscom shed 2.4 percent; with Chemgenex, Pharmaxis, Psivida, QRX and Tissue Therapies down more than one percent.

CELLMID

Cellmid jumped 216 percent on completed development of the first fully-validated enzyme-linked immunosorbent assay (Elisa) for the accurate measurement of midkine in blood.

Cellmid said it had developed the “highly sensitive and robust assay” for the accurate measurement of midkine in serum or blood, as a biomarker for cancer, using the immunoassay development expertise of Germany’s Biogenes GmbH.

Cellmid said it would apply for Conformité Européenne (CE) mark of the test to confirm its position as a gold standard for midkine measurement.

The company said its reliable and reproducible midkine elisa (MK Elisa) was “essential for the validation of cancer diagnostic and prognostic applications” and would enable the wider scientific community engaged in midkine research to confidently generate data for diagnostic and therapeutic applications.

Cellmid said Biogenes had completed the manufacture of the first batch of MK Elisa kits which were available for direct purchase by the global research market.

The company said it might make the MK Elisa tests available through research products suppliers in the future.

Cellmid said the tests would be used for its in-house diagnostic programs, including the recently commenced CK3000 program at Japan’s Kumamoto University Medical School.

Cellmid said the MK Elisa test was highly sensitive with the limit of detection set at eight pictogram per millilitre (8pg/ml), which was “well below midkine levels in normal human serum”.

The company said the tests dynamic range was 25pg/ml to 1000pg/ml facilitating measurement from diverse samples.

Cellmid said the MK Elisa test was selective with no cross-reactivity with the closely-related protein pleiotrophin, the only other protein in the midkine family.

Cellmid said the test recognized all major species of midkine including human, mouse, dog and pig making it highly suitable for animal studies and veterinary cancer diagnostic applications.

The company said the test was robust, highly reproducible and that midkine was an embryonic cytokine that was attracting wide interest as a cancer biomarker and potential diagnostic and prognostic tool.

Cellmid said midkine had very limited expression in healthy adults, but was detectable in high quantities in the blood and urine of patients with a wide variety of cancers and that midkine levels had been found to correlate with progression and malignancy in certain cancers.

Validation data on midkine as a suitable biomarker for cancer detection and prognosis was the subject of over 50 peer reviewed publications, the company said.

Cellmid said it held key patents in all major territories for the use of midkine in the early detection, diagnosis and prognosis of cancer and had licenced its technology to two companies for the development of lung and bladder cancer diagnostic tests.

Cellmid chief executive officer Maria Halasz said Biogenes had made a “superb technical contribution to this difficult assay development project” which was “instrumental in the program’s success”.

Cellmid’s head of product development Darren Jones said that the technical specifications of the MK Elisa test would be introduced on November 4, 2010 to the delegates of the Cellmid-hosted Excellence in Midkine Research Conference in Sydney.

Cellmid was up 4.1 cents or 215.8 percent to six cents with 377.6 million shares traded.

AUSTRALIAN RESEARCH COUNCIL

The Australian Research Council has called for comment on a consultation paper proposing to 'streamline' its research discovery program.

The Council said in a media release that the consultation paper "outlines a number of changes that aim to increase support for early-career researchers, reduce the overlap of fellowships within the Discovery Program and streamline the Discovery Projects scheme".

The paper is available at http://www.arc.gov.au/ncgp/dp/dp_consultation.htm, with the consultation period closing on December 1, 2010

At the same time the Australian Research Council said that it intended to create the Discovery–Early Career Researchers Awards to give "researchers at the start of their careers more opportunities to obtain funding for their research projects".

Australian Research Council chief executive officer Prof Margaret Sheil said the program would introduce a new and more flexible component to the Council's national competitive grants program.

"This new scheme component will provide more focused support for researchers and create more opportunities for early-career researchers in both teaching and research, and research-only positions," Prof Sheil said.

"The scheme will also capitalize on two specific attributes [of] early-career researchers, namely, the high proportion of female and international applicants," Prof Sheil said.

The Council media release quoted the Minister for Innovation Senator Kim Carr welcoming the proposal.

"This new award will be a key component of the Gillard Labor Government's strategy to build future research capacity," Senator Carr said.

"It creates new opportunities for the next generation and it builds on the great work of the ARC to ensure we attract and retain the best and brightest researchers in Australia," Senator Carr said.

VIRALYTICS

Viralytics says it has lodged an investigational new drug application for a 54-patient phase II trial of Cavatak for melanoma with the US Food and Drug Administration.

Viralytics said that subject to review by the FDA, each patient would receive up to 10 injections of Cavatak over six months.

The company said that at each of the scheduled 10 visits the patients would receive an injection of Cavatak into multiple lesions.

Viralytics said the dosing schedule was designed to maximize the direct killing of tumors and generate potential anti-tumor immune responses initiated by the patient's immune system against Cavatak-infected tumor cells.

The company said the proposed treatment regimen was a significant increase in dosing frequency from the initial phase I melanoma safety studies, where the company was permitted to inject a single dose of Cavatak into a single tumor.

Viralytics said the phase II study was expected to be held in the US, Europe and Australia.

The company said the 1200 page application had sections discussing the mode of action of the technology, listing in detail the clinical trial data achieved to date and detailed descriptions of the preclinical toxicology studies undertaken and contained in-depth technical descriptions of the Cavatak production process.

The lodgment of this application was a significant achievement, the company said.

Viralytics was up 0.1 cents or three percent to 3.4 cents with 4.7 million shares traded.

IMMURON

Immuron has presented posters detailing its preclinical and phase I/II trial results for the treatment of the liver disease non-alcoholic steato-hepatitis and metabolic syndrome.
Immuron said the posters were presented at the American Association for the Study of Liver Disease conference in Boston.
The company said the posters reported on Immuron's results in a phase I/II clinical trial of its hyperimmune bovine colostrum product IMM124-E for the treatment of non-alcoholic steato-hepatitis (Nash) and aspects of metabolic syndrome (BD: Aug 23, 2010) and earlier animal studies.
Immuron said the clinical trial was completed at the Hadassah Hebrew University Medical Center and showed that oral administration of IMM124-E was safe and effective and exerted an immuno-modulatory effect in patients with insulin resistance or type 2 diabetes, hyperlipidemia and non-alcoholic steato-hepatitis.
The company said that all primary and secondary endpoints were successfully achieved with improvements observed across all clinical parameters and the product was well tolerated and no drug related adverse events were recorded during the clinical trial.
Immuron said the primary endpoint of an improvement in liver enzyme levels (AST, ALT, AP and GGT) was attained and the secondary endpoints of improvement in levels of insulin resistance and lipid levels were measured using the HBA1C test, and oral glucose tolerance test and lipid tests.
The company said the majority of patients improved in measures of insulin resistance with improvement in physiological markers of metabolic syndrome (GLP-1 and Adiponectin levels).
Immuron said that 70 percent of patients showed a significant increase in regulatory T cell measurements.
Abstracts of the posters have been published in the journal '*Hepatology'* and are at Immuron's website: http://www.immuron.com/index.php/products/publications
Immuron's chief executive officer Dr Grant Rawlin said the clinical trial demonstrated the company had "a serious product candidate for the treatment of Nash, one of the most common liver diseases in the western world".
The company said there was no approved or effective treatment for non-alcoholic steato-hepatitis.
The posters were entitled '
Alleviation of insulin resistance and liver damage by oral administration of ETEC colostrums is mediated by increased GLP-1, adiponectin serum levels and Tregs: Results of a phase I/II clinical trial in Nash' and 'Induction of CD4+CD25+FOXP3+ regulatory T cells by oral administration of IgG enhanced colostrums suppressed the chronic inflammatory state in OB/OB mice alleviating the insulin resistance and liver injury'.
Immuron was up 0.1 cents or 1.2 percent to 8.6 cents.

BROADVECTOR

Broadvector says Alpha Securities has been appointed lead manager of its initial public offering which has been extended to November 30, 2010.
Broadvector chief executive officer Dr Andrew Bray told Biotech Daily that the company hopes to commercialize its gene-therapy platform technology but was yet to reach the minimum capital raise of $5 million (BD: Sep 6,13, 2010).
Dr Bray said that Alpha's director George Karantzias had been "very proactive" since the appointment.
Alpha has previously raised funds for Stirling Products.

ELLEX MEDICAL LASERS

Ellex says it has secured a second distribution deal with Italian-based Centervue to market the DRS retinal camera in the US.

Ellex said it had distribution rights for Centervue's macular integrity assessment technology (Maia) fundus perimetry system in the US and Australia (BD: Oct 12, 2010).

Ellex said the DRS was a high-resolution, non-mydriatic, digital retinal camera using an automated process to capture high-quality images of the retina with minimal operator involvement.

The company said the DRS was expected to open up new market segments in the US and broaden its customer base to include optometrists, in addition to ophthalmologists.

Ellex chief executive officer Simon Luscombe said DRS was "a perfect fit for our existing portfolio of retinal treatment lasers, as well as the recently-added MAIA fundus perimetry system".

With the addition of the DRS system our customers will now be able to perform all facets of patient diagnosis in the management of retinal disease," Mr Luscombe said.

Ellex said it expected the DRS "to generate high-volume sales, contributing significantly to increased growth during the 2011 financial year".

"Every optometric and retinal practice needs a retinal camera," Mr Luscombe said.

Ellex said its third-party distribution business generated revenues of about $7 million in the 2010 financial year over and above sales of the company's proprietary products and technologies.

Ellex fell half a cent or 1.9 percent to 26 cents.

NOVOGEN

Novogen has appointed corporate advisor Peter Scutt as a director effective immediately.

Novogen said Mr Scutt was a consultant to specialist corporate advisory and investment house Spark Capital and previously worked for Texel Capital and BT Venture Partners.

Novogen fell half a cent or 4.35 percent to 11 cents.

AGENIX

Agenix has appointed Dr Danyi Zhang to its China scientific advisory board "as product champion for Thromboview".

Agenix's chairman Nick Weston said Dr Zhang would help Agenix with strategic decisions in commercializing the company's lead diagnostic indicator Thromboview in China and for global pharmaceutical markets.

Agenix said its strategy was to twin Thromboview with novel oral anti-coagulant therapies for use as a diagnostic.

Agenix said Dr Zhang was the founder and chief medical officer of the US-based Vital Strategic Research Institute and had worked in the biopharmaceutical industry for more than 15 years in drug development, medical affairs and strategic planning.

The company said Dr Zhang previously worked for Bristol-Myers Squibb as the medical director of global medical affairs.

Agenix was unchanged at 2.2 cents.