



Biotech Daily

Wednesday November 2, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: LIVING CELL UP 33%; ANTISENSE DOWN 10%**
- * **GENETIC TECHNOLOGIES, IMMUNAID TIMED CHEMOTHERAPY PATENT**
- * **GENERA CLAIMS 'EXCELLENT' PAPTYPED VALIDATION RESULTS**
- * **LIVING CELL COMPLETES DIATRANZ OTSUKA JOINT VENTURE**
- * **JCP TAKES 5% OF RESMED**
- * **PHOSPHAGENICS LICENCES TPM-DICLOFENAC TO INDIA'S THEMIS**
- * **ATCOR SIGNS \$867k CONTRACT EXPANSION**
- * **SHAREHOLDERS BLOCK HEALTHLINX REMUNERATION CEO OPTIONS**
- * **VIRALYTICS APPOINTS DR KEVIN HARRINGTON TO ADVISORY BOARD**

MARKET REPORT

The Australian stock market fell 1.14 percent on Wednesday November 2, 2011 with the S&P ASX 200 down 48.3 points to 4184.6 points.

Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, three traded unchanged and seven were untraded.

Living Cell was the best, up two cents or 33.3 percent to eight cents with 5.8 million shares traded.

Avita, Mesoblast and Prima climbed five percent or more; Genetic Technologies, Neuren and QRX were up more than three percent; Psivida rose 2.1 percent; with Anteo and Clinuvel up more than one percent.

Antisense led the falls, down 0.1 cents or 10 percent to 0.9 cents, with 9.3 million shares traded.

Sunshine Heart lost 8.9 percent; Allied Health fell 7.7 percent; Nanosonics fell 6.3 percent; Benitec, Cellmid, Optiscan and Starpharma fell five percent or more; Cochlear, Heartware and Phylogica were down four percent or more; Prana and Viralytics lost more than three percent; Bionomics and Pharmaxis shed more than two percent; with Tissue Therapies and Universal Biosensors down more than one percent.

GENETIC TECHNOLOGIES, IMMUNAID

Genetic Technologies says 71.7 percent subsidiary Immunaid has been awarded a European patent for cancer treatment, based on patient immune cycle monitoring. Genetic Technologies said the patent was entitled 'Method of Therapy' with European Patent number EP1692516 and covers the immune cycle monitoring of individual patients to determine the optimal time to deliver treatment.

In an Immunaid media release distributed by Genetic Technologies the company said it was a private company "founded a decade ago to explore the concept developed by inventor Martin Ashdown that the immune system switches itself on-and-off in a continuous, repeating cycle in patients with certain diseases, including auto-immune disease and that treatment should be timed to support the body's own efforts to fight off such disease".

Immunaid said Mr Ashdown a research fellow at the University of Melbourne's Medicine Faculty expanded his concept to include cancer and several degenerative diseases.

The company said Mr Ashdown and the Immunaid research team "demonstrated that the immune system of cancer patients undergoes a repeating cycle and that the administration of treatment at certain critical moments within that cycle can significantly improve the clinical outcome".

Immunaid is co-owned with Genetic Technologies by Martin and Luisa Ashdown and Genetic Technologies founder Dr Mervyn Jacobson.

Immunaid chief executive officer Dr Jacobson said that "once we realized this immune cycle is real and measurable, we postulated that the administration of chemotherapy and other anti-cancer therapies should be timed to work with each individual patient's immune system to attack the cancer".

"The results then spoke for themselves," Dr Jacobson said.

Immunaid said that Royal Adelaide Hospital surgical consultant Prof Brendon Coventry conducted extensive clinical trials over several years.

"Treatments randomly given without consideration to a patient's immune cycle explains why some patients achieve a complete recovery and others do not," Prof Coventry said.

Immunaid said that the Mayo Clinic was conducting an independently-funded, 59-patient, phase II clinical trial to further assess the influence of timed delivery of conventional chemotherapy for patients with cancer.

Patients with an established biorhythm receive temozolomide orally on the recommended day for 5 days, with treatment repeats every 21-42 days until disease progression or unacceptable toxicity. Patients without an established biorhythm will receive temozolomide on days 1-5, with courses repeating every 28 days until disease progression or unacceptable toxicity.

The trial details are at: <http://clinicaltrials.gov/ct2/show/record/NCT01328535>.

The company said hospitals and universities in Australia were conducting trials on cancer and other diseases, including multiple sclerosis and human immunodeficiency virus.

Mayo Clinic melanoma group chair Dr Svetomir Markovic said the discovery of the regulated immune response cycle in cancer patients "is potentially of immense clinical significance with profound public health implications".

The company said that an analysis of 63 clinical trials published since 2000 showed the average complete response rate, or becoming cancer-free, in late-stage patients across a wide range of cancers was seven percent.

"Timed delivery of chemotherapy appears to offer added therapeutic benefit in the treatment of metastatic melanoma," Dr Markovic said.

Genetic Technologies was up half a cent or 3.7 percent to 14 cents.

GENERA BIOSYSTEMS

Genera says its Papttype diagnostic test for human papillomavirus, has “achieved excellent results” in an independent study in a London-based medical research institute. Genera executive chairman Lou Panaccio told Biotech Daily that confidentiality provision prevented the company naming the London institute or providing detailed results at this time.

In its media release to the ASX, Genera said that 1,099 samples from a patient population presenting with mild to moderate cervical cell anomalies were tested to assess the sensitivity and specificity of the seven commercially available molecular tests designed for the detection of human papillomavirus (HPV), as measured against histology obtained by colposcopy.

The company said that each sample, except for 32 samples of insufficient quality, was analyzed by all tests in the panel and Papttype performed as well as, and in some cases better than, the other high-sensitivity tests in the panel.

Importantly, Papttype was the only test in the panel able to differentiate all 14 high risk HPV types, as well as the two most common low risk HPV types, Genera said.

Genera chief scientific officer Dr Karl Poetter said the data was obtained “in a rigorous format from a world respected independent laboratory”.

“We are very pleased with the results and especially delighted with the demonstration of Papttype’s balance of high sensitivity and high specificity - a critical feature of any test expecting to be taken up by physicians and pathology providers as a screening test for women at risk for cervical cancer,” Dr Poetter said.

Genera said that human papillomavirus caused cervical cancer and completion of the study was a significant milestone, expected to play a substantial role in progressing the commercialization of the Papttype test.

The company said Papttype had regulatory approval and was available for clinical use in Australia and Europe.

“It would be hard to overstate the significance of obtaining compelling data from a global leader in HPV research in furthering our efforts to commercialise Papttype,” Mr Panaccio said.

“While there is broad awareness of Papttype among potential strategic partners following our previous discussions, this formal international validation of Papttype that we have now obtained will be used as the basis for revisiting partnering discussions in coming weeks and months,” Mr Panaccio said.

“At the same time, Genera is continuing in its efforts to have a number of additional commercial pathology laboratories commence routine use of Papttype,” Mr Panaccio said.

“The data that we have now obtained will also be of value in our dialogue with potential customers,” he said.

“Notably, Genera has always thought of Papttype as a screening tool, a first line test along with the standard Pap smear for early detection of patients at risk for cervical cancer,” Mr Panaccio said.

“The HPV screening market is expected to grow into a \$US1 billion per annum market opportunity and these results firmly justify our belief in Papttype becoming a highly competitive screening tool,” Mr Panaccio said.

Genera was untraded at 14.5 cents.

LIVING CELL TECHNOLOGIES

Living Cell says it has completed its 50/50 joint venture with Otsuka Pharmaceutical Factory to create Diatranz Otsuka to commercialize Diabecell for type 1 diabetes.

Living Cell said it had transferred Diabecell assets valued at \$25 million and Otsuka had deposited \$25 million to Diatranz Otsuka (BD: Oct 19, 2011).

The company said the Diabecell assets included patents, trademarks, manufacturing, research and development facilities, as well as the herd of bio-certified designated pathogen-free pigs, which provide the islets of Langerhans for transplant.

Living Cell said it had granted a royalty-free licence to Diatranz Otsuka to use its encapsulation technology to treat diabetes.

The company said it would supply testing, research and development, management and administrative services to the joint venture at market rates.

Living Cell was up two cents or 33.3 percent to eight cents with 5.8 million shares traded.

PHOSPHAGENICS

Phosphagenics says it has licenced its transdermal tocopheryl phosphate mixture (TPM) diclofenac to Mumbai's Themis Medicare for use in the Indian market.

Phosphagenics said that diclofenac was a non-steroidal anti-inflammatory drug (NSAID) that reduced pain by reducing inflammation and was used as an active ingredient to reduce pain and inflammation in a tablet form as well as in topical formulations, most commonly marketed as Voltaren Emulgel.

The company said that in 2009 it announced clinical results that clearly showed more rapid absorption and deeper penetration of TPM-diclofenac than Voltaren.

Phosphagenics said at that time that the 12-patient phase Ib trial showed that TPM increased absorption by 380 percent (BD: Sep 10, 2009).

The company said in vitro comparative studies showed that its TPM formulation delivered more diclofenac through human skin than commercial products sold in India.

Phosphagenics said the licence was its first commercial deal in India and its first licencing agreement of its diclofenac product.

The company said that Themis would pay an undisclosed up-front fee and double-digit royalty payments on sales.

Phosphagenics said that Themis manufactured, formulated and marketed its own products in four state-of-the-art manufacturing facilities.

The company said Themis was obligated to launch the over-the-counter TPM-diclofenac

Phosphagenics chief executive officer Dr Esra Ogru said the deal was "endorsement of the superior delivery capabilities of the patented TPM technology as well as a new revenue source for the company".

"We expect this to lead to other licensing arrangements for diclofenac in other regions of the world," Dr Ogru said.

Phosphagenics was unchanged at 18 cents with 2.1 million shares traded.

RESMED

Melbourne's JCP Investment Partners has become a substantial shareholder in Resmed with the acquisition of 78,431,898 shares or 5.04 percent.

The initial substantial shareholder notice said that JCP's most recent and largest transaction was the acquisition of 6,534,800 shares for \$17,257,583 or an average price of \$2.64 a share.

Resmed was up two cents or 0.75 percent to \$2.69 with 2.6 million shares traded.

ATCOR MEDICAL

Atcor Medical says it has signed a \$US900,000 (\$A867,000) expansion to a contract to supply Sphygmocor systems and services to an undisclosed pharmaceutical company. Atcor said this transaction took total pharmaceutical contracts to \$US4 million in the past five months.

Atcor chief executive officer Duncan Ross said the pharmaceutical sector “continues to perform well and offers significant opportunity for Atcor’s growth”.

The company said Sphygmocor was a non-invasive measure of central aortic pressure. Atcor was unchanged at eight cents.

HEALTHLINX

Healthlinx shareholders have defeated the company’s remuneration report and the issue of 5,600,000 options to managing director Nick Gatsios.

The remuneration report was defeated by 39,003,259 proxy votes against to 10,810,702 proxy votes in favor.

Mr Gatsios’ options were defeated by 34,519,259 proxy votes against to 15,161,142 proxy votes in favor.

Directors Stewart washer and John Evans were reelected with more than 57 million votes in favor and fewer than 500,000 proxy votes against.

The issue of securities to Dutchess Opportunity Fund and the employee and officer option plan were approved by a similar margin.

Healthlinx was unchanged at 1.6 cents with 1.3 million shares traded.

VIRALYTICS

Viralytics has appointed Dr Kevin Harrington to its scientific advisory board.

Viralytics said that Dr Harrington was a reader in biological cancer therapies at London’s Institute of Cancer Research and an honorary consultant clinical oncologist at the UK’s Royal Marsden National health Service Foundation Trust.

The company said Dr Harrington specialized in developing treatment regimens using viruses to selectively destroy cancer cells.

Viralytics said Dr Harrington studied medicine at London’s St Bartholomew’s Hospital and began work on head and neck cancer while a Ph D student at Hammersmith Hospital.

The company said Dr Harrington completed post-doctoral research in molecular medicine at the Mayo Clinic in Minnesota before joining the Institute of Cancer Research in 2001 and heads a team that investigated targeted cancer therapy.

Viralytics said the goal of the Institute team’s work was to develop therapies in which gene therapy and oncolytic virotherapy were combined with standard cytotoxic agents, such as radiotherapy and/or chemotherapy.

Viralytics chief scientific officer Prof Darren Shafren said that Dr Harrington’s knowledge of virotherapy and viral based combination studies was “a welcome addition to the company’s existing knowledge base”.

Viralytics fell 1.5 cents or 3.3 percent to 44.5 cents.