



Biotech Daily

Thursday April 5, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: AVITA UP 15%, LIVING CELL DOWN 11%**
- * **CANCER CRC: 'CTX-0294945 IN-VIVO SUCCESS WITH AVASTIN'**
- * **POSITIVE 36-MONTH FOLLOW-UP FOR ALLIED'S CARDIOCEL PATCH**
- * **EURO-PATENT, US TRADEMARK FOR AVITA'S RECELL SPRAY-ON SKIN**
- * **REGENEUS TREATS 40 FAT STEM CELL TRIAL PATIENTS; IPO BY JUNE**
- * **RESONANCE 'PROGRESS ON MRI TEST FOR FIBROSIS, FATTY LIVER'**
- * **ITL SELLS 'TROUBLED MALAYSIAN DISTRIBUTOR'**
- * **HIV DIAGNOSTIC, MICRO X-RAY WIN \$250k VICTORIA GRANTS**
- * **SOCIETY FOR BIOCHEMISTRY AND MOLECULAR BIOLOGY 2012 GONGS**

MARKET REPORT

The Australian stock market fell 0.33 percent on Thursday April 5, 2012 with the S&P ASX 200 down 14.1 points to 4,319.8 points.

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

Avita was the best, up three cents or 15.4 percent to 22.5 cents with 1,1 million shares traded, followed by Prana up 9.7 percent to 17 cents, with 232,956 shares traded.

Antisense and Ellex climbed more than five percent; Allied Health was up 3.45 percent; Genera and Prima rose more than two percent; with Acrux, CSL and Mesoblast up more than one percent.

Living Cell led the falls, down 0.9 cents or 11.25 percent to 7.1 cents, with 100,000 shares traded, followed by Phylogica down 9.1 percent to five cents with 2.1 million shares traded.

Psivida lost 8.8 percent; Patrys was down 6.25 percent; Impedimed and Tissue Therapies fell four percent or more; Biota and Nanosonics were down more than three percent; Anteo, Genetic Technologies, Phosphagenics, QRX, Resmed and Starpharma shed two percent or more; with Bionomics, Reva, Sirtex and Viralytics down more than one percent.

CANCER THERAPEUTICS COOPERATIVE RESEARCH CENTRE

The Cancer Therapeutics Cooperative Research Centre says it has positive preclinical results for CTX-0294945 as an adjuvant therapy with Avastin (bevacizumab) for cancer. The CRC said the data was presented in a poster entitled: 'Combination of CTX-0294945 a highly selective inhibitor of focal adhesion kinase with bevacizumab in pre-clinical models of breast cancer' at the American Association for Cancer Research meeting in Chicago and said that CTX-0294945 was a highly-selective small molecule inhibitor of focal adhesion kinase, a non-receptor tyrosine kinase implicated in solid tumor maintenance and progression.

The CRC said that CTX-0294945 was an appropriate candidate for combination therapy in a range of cancers and in the study, CTX-0294945 was combined with the anti-angiogenic antibody Avastin in an in-vivo orthoptic model of triple negative breast cancer.

The CRC said that Avastin was widely used in the clinic but its efficacy could be limited and short-lived, but CTX-0294945 significantly augmented the effectiveness of Avastin in limiting tumor growth and significantly increased the duration of response.

The Centre said that CTX-0294945 appeared to inhibit tumor revascularization and macrophage infiltration even after Avastin therapy has stopped.

Cancer Therapeutics Warwick Tong said the Centre was "delighted that this, our first therapeutic cancer candidate has made such a strong preclinical showing, achieving proof of concept in combination with Avastin".

ALLIED HEALTHCARE GROUP

Allied says that 36-month follow up of its phase II paediatric trial of Adapt Cardiocel shows the cardiac patches had no complications and no evidence of significant calcification.

Allied said the Cardiocel was a collagenous-based bioprosthetic device, made of bovine pericardium tissue and treated with subsidiary Celxcel's Adapt tissue engineering process. Allied said that, so far, 14 patients had been followed-up after two years, with five patients followed-up to three years and all patients were free of patch-related complications or adverse events.

Allied said that echo-cardiographic results showed intact haemodynamics or blood flow with no evidence of significant calcification of the Cardiocel patch at 24 and 36-months.

Allied managing director Lee Rodne said the follow-up data "further supports the data for the Celxcel technology, in particular the prevention of calcium build up in tissue post implantation".

"This is a major market differentiator for products using the technology and provides major benefit for patients longer term," Mr Rodne said.

The company said that in May 2008, 30 patients aged from three months to 14 years, were implanted with the Cardiocel patches.

Allied said that the study included paediatric patients diagnosed with congenital heart disease that required a tissue patch for corrective surgical repairs during major open-heart surgery at the Universitas Hospital, in Bloemfontein, South Africa.

Allied said that the follow up patients had a cardiac clinical evaluation, a full blood count, and an echocardiographic study to evaluate haemodynamic compatibility, evidence of calcification and the general efficacy of the Cardiocel patch.

Celxcel chief executive officer Bob Atwill said that following the "encouraging results we will be actively reviewing all patients in the phase II study in order to get valuable additional long-term data for these paediatric [congestive heart disease] patients," Mr Atwill said.

Allied was up 0.1 cents or 3.45 percent to three cents.

AVITA MEDICAL

Avita says it has been granted a European patent entitled 'Cell Suspension Preparation Technique and Use' and a US trademark for 'Spray-On Skin'.

Avita said the European grant covered broad claims related to the preparation of a cell suspension comprised of the patient's own epithelial cells, or autologous suspension, the therapeutic use of the cell suspension and, importantly, a composition of matter claim for the suspension of autologous cells.

The company said that the technology was incorporated in the company's Recell product for chronic and acute wounds along with reconstructive and aesthetic procedures.

The company said that Recell was a stand-alone, point-of-care device that allowed the harvesting of a sample of a patient's skin and, via an enzymatic and mechanical process, the disaggregation of the constituent cells; the incorporation of the disaggregated and isolated cells into a suspension consisting of mature and immature epithelial cells as well as undifferentiated skin cells; and the delivery and application of this therapeutic cellular suspension to the patient - and each of these aspects was covered by the patent.

Avita said the US Patent and Trademark Office had registered the trademark Spray-On Skin.

Avita was up three cents or 15.4 percent to 22.5 cents with 1.1 million shares traded.

REGENEUS

Regeneus says Macquarie Bank will lead manage its initial public offer, which is expected to be launched before June 30, 2012, subject to market conditions.

Last year, Regeneus chairman John Martin told Biotech Daily that the company had a 40-patient, randomized, double-blind, placebo-controlled study at Sydney's Royal North Shore Hospital to evaluate the efficacy and safety of autologous non-expanded adipose (fat) derived stem cells in the treatment of knee osteoarthritis (BD: Nov 29, 2011).

Mr Martin said Regeneus had conducted the procedure on more than 400 dogs through its animal health division and the company expected to complete the human trial by September 2012 with results evaluated by the end of the 2012.

In a March 2012 shareholder newsletter, Regeneus said that all 40 patients in the Royal North Shore Hospital trial had received treatment and final data would be collected by the end of September 2012, with results available by April.

Regeneus said that since Hiqcell became commercially available in Sydney in late 2011, more than 60 patients had been treated for osteoarthritis and tendonitis.

The company said that the UK's Medicines and Healthcare products Regulatory Agency, "confirmed our path is clear for early commercialization of Hiqcell in the UK".

Regeneus said it had launched an allogeneic fat stem-cell product Cryoshot to treat osteoarthritis and tendonitis in dogs and horses.

Mr Martin told Biotech Daily that Regeneus was a public unlisted company.

RESONANCE HEALTH

Resonance Health has completed recruitment and magnetic resonance imaging (MRI) scanning of all patients in a study to develop an MRI-based test for liver fibrosis.

Resonance said it was waiting for results from external laboratories to complete the assessment of its MRI technology for measuring liver fibrosis and that final testing of the Hepafat Scan technology was underway to develop an accurate MRI test for fatty liver, ahead of a submission of a 510(K) application to the US Food and Drug Administration.

Resonance fell half a cent or 31.25 percent to 1.1 cents.

ITL

ITL says it has a conditional sale of 'troubled Malaysian distributor' ITL SEA Sdn Bhd and its wholly owned subsidiaries, expected to be effective from January 1, 2012.

The company said the Kuala Lumpur-based subsidiary, marketed and distributed medical equipment and consumables to Malaysian hospitals and medical centres.

ITL said the decision "reflects both the lack of strategic fit of this distribution-only business and the ongoing depressed market conditions in Malaysia" and the management buyout was the best outcome for shareholders in disposing of the loss-making business.

The company said the Malaysian business was unrelated to its successful manufacturing company ITL Asia Pacific Sdn Bhd, based at Ipoh in Malaysia, producing biological safety sampling devices primarily for the blood and laboratory industries.

ITL said it expected to conclude the agreement by May 2012 and raise about \$1.0 million, with an accounting treatment showing a once-off loss of about \$1.0 million.

The company said the impact of the sale on second-half group operating profit, excluding the once-off accounting loss, was expected to be neutral to positive and on conclusion of the transaction, the ITL Group expected to be debt free.

ITL was up one cent or 7.7 percent to 14 cents.

VICTORIA GOVERNMENT

The Victoria Government will provide goods, services, facilities or advice valued up to \$250,000 each to three projects including an HIV diagnostic and mobile X-ray system.

A media release from Victoria's Technology Minister Gordon-Rich Phillips said the Small Technologies Industry Uptake Program funding would be awarded to the private company See-D4 to develop a rapid, low-cost diagnostic test allowing for more efficient treatment and management of the HIV virus.

See-D4's Prof David Anderson told Biotech Daily that he developed the technology at Melbourne's Burnet Institute.

The Government media release said that a cartridge and reader would be developed to accurately test for CD4 cells, the biomarker cells that are used by doctors to decide when to begin treatment during HIV infection.

The media release said that a second project by private company Micro-X would develop a mobile X-ray machine that could be brought to a hospital patient's bedside, with potential new applications in veterinary and mobile medical fields and a new form of nano-carbon would be used to develop the X-ray tube.

The third project entitled Nufarm would develop next-generation agriculture products with improved shelf-life, and lower production costs, using an advanced polymerization process developed by CSIRO.

Mr Rich-Phillips said the State Government supported the innovative projects, "all of which have the potential to create new jobs and investment in Victoria if they are successfully commercialized".

Mr Rich-Phillips said the program gave Victorian businesses the opportunity to develop more efficient production techniques and new high-value products.

"There is keen interest within industry to adopt new technologies and boost productivity, particularly within the manufacturing sector," Mr Rich-Phillips said.

"So far around 70 feasibility, technical and trial vouchers, providing varying amounts of financial support, have been provided since the STIUP program began," Mr Rich-Phillips said.

AUSTRALIAN SOCIETY FOR BIOCHEMISTRY AND MOLECULAR BIOLOGY

The Australian Society for Biochemistry and Molecular Biology highest award for 2012 has been won by Walter and Eliza Hall Institute director Prof Doug Hilton.

The Society says it “aims to advance biochemistry and molecular biology in Australia, facilitating research and education, and interfacing with business and the community”.

The Society said that its leading award, the Lemberg medal, would be presented to Prof Hilton at the Society’s Combio meeting in September 2012.

The Society said that the Lemberg medal was awarded annually to an Australian scientist who is deemed to have made ongoing contributions to biochemistry or molecular biology.

The Society said that the Beckman Coulter discovery science award was won by Prof Marc Wilkins of the University Of New South Wales; Monash University’s Prof James Whisstock won the Merck Millipore research medal; WEHI’s Dr Erinna Lee won the Life Technologies Edman award; the Netherlands Cancer Institute’s Dr Ian Majewski won the Boomerang award; the University Of Sydney’s Prof Gareth Denyer won the Life Technologies Education award and WEHI’s Dr Christopher Tonkin won the Bioplatforms Australia Award.

ASBMB Fellowships were awarded to WEHI’s David Riglar, the University of Melbourne’s Cheryl Chia and Helena Safavi-Hemami, as well as the University Of New South Wales’ Ignatius Pang