Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 15%, GENERA DOWN 17%**

*** OSPREY BEGINS CATHETER-BASED LIMB RECOVERY TRIAL**

*** BENITEC, UNIQURE CROSS-LICENCE ddRNAi, AAV5 DELIVERY**

*** AUSTRALIAN ETHICAL TAKES 5% OF UNIVERSAL BIOSENSORS**

*** CORRECTION: GI DYNAMICS**

*** EASTLAND PROMOTES CEO, CFO; LOOKS FOR NEW PROJECTS**

MARKET REPORT

The Australian stock market fell 0.62 percent on Tuesday December 4, 2012 with the S&P ASX 200 down 27.9 points to 4,503.6 points.

Ten of the Biotech Daily Top 40 stocks were up, 14 fell, 14 traded unchanged and two were untraded.

Impedimed was the best, up 1.5 cents or 15 percent to 11.5 cents with 84,770 shares traded, followed by Genetic Technologies up 13.3 percent to 8.5 cents with 986,534 shares traded.

Compumedics climbed 9.1 percent; Patrys was up 7.1 percent; Phylogica was up 4.2 percent; Alchemia, Tissue Therapies and Viralytics were up more than three percent; Optiscan and Psivida rose two percent or more; with CSL up 0.9 percent.

Genera led the falls, down 2.5 cents or 16.7 percent to 12.5 cents with 550,000 shares traded.

QRX lost 6.3 percent; Mesoblast was down 5.2 percent; Clinuvel, Prana and Starpharma fell more than four percent; Heartware and Phosphagenics were down more than three percent; Living Cell shed two percent; GI Dynamics, Pharmaxis, Resmed, Sirtex and Universal Biosensors were down more than one percent; with Acrux and Cochlear down by less than one percent.

OSPREY MEDICAL

Osprey says it has begun a two-part, 25-patient pilot trial investigating the delivery of high dose antibiotics to diabetic patients with life or limb-threatening foot infections.

Osprey said that using a system based on its Cincort technology for removing cardiac dye. the patients at the Royal Melbourne Hospital would have catheters inserted in their femoral artery and femoral vein to deliver existing antibiotic therapies in a more targeted and aggressive manner.

Osprey chief executive officer Mike McCormick told Biotech Daily the trial would begin with a five-patient safety and tolerability study and be followed by a randomized 20 patient efficacy study.

“In Europe both of those trials might be sufficient to get European approval,” Mr McCormack said. “They also may be sufficient to get [Australian] TGA approval.”

“Those trials probably are not sufficient to get US FDA approval and there will be probably be a requirement by the US Food and Drug Administration to do a pivotal clinical trial,” Mr McCormack.

Mr McCormack said he expected tto have results from the first five patients by October 2013 with two year results on the latter 20 patients by the end of 2014.

In a media release, Osprey said the randomized clinical outcomes study in 20 patients would compare the effectiveness of the limb recovery system with standard dose intravenous delivery of antibiotic therapy, for the treatment of severe limb infections.

Osprey was that in July 2012, it received approval for a $1.1 million grant from the Victorian Government’s Market Validation Program to conduct a first-in-man clinical study on its percutaneous limb perfusion technology, referred to as the Limb Recovery System.

The company said it had partnered with the Royal Melbourne Hospitals’ Diabetic Foot Unit for the two year study.

Mr McCormick said the Limb Recovery System technology had “the potential to significantly improve the quality of life outcomes for patients with diabetes who have lower limb infections”.

The company said that the Limb Recovery System was originally developed by the Baker IDI Heart and Diabetes Institute’s Prof David Kaye and Dr Melissa Byrne and their pre-clinical research team in Melbourne.

Osprey said the Limb Recovery System enabled the circulation of the limb to be isolated and separated from the general circulatory system, by creating an artificial circuit through inserting catheters into the major artery and vein of the lower limb permitting the delivery of antibiotic drugs at high doses that were otherwise unachievable with standard care.

The company said that more than 360 million people worldwide had diabetes and this number was expected to increase by more than 50 percent by 2030.

Osprey said that people with diabetes were particularly prone to diabetic limb and foot infections due to insufficient blood flow and impaired wound healing.

The company said that standard oral or intravenous delivery of antibiotics was often ineffective in these patients because dosage levels could not be achieved at a sufficient level at the site of the limb infection.

Infections of the lower limb were the leading cause of amputations globally, leading to increased rates of hospitalization and higher healthcare costs throughout the developed world.

The head of the Royal Melbourne Hospital’s diabetic foot unit Prof Paul Wraight said the incidence of diabetes-related lower limb infections was increasing.

“The current treatment options can narrow significantly if the infection becomes life threatening,” Prof Wraight said.

Osprey was unchanged at 38 cents.

BENITEC BIOPHARMA

Benitec has a cross-licencing agreement with Uniqure BV for Uniqure's program on Huntington's disease and Benitec's hepatitis B program.

Benitec said it had licenced its DNA-directed RNA interference (ddRNAi) gene silencing technology to the Amsterdam-based Uniqure to develop a treatment for Huntington's disease.

The company said that, in turn, Uniqure had provided Benitec a non-exclusive licence to use its AAV-5, based on adeno-associated viral vectors delivery technology for its gene silencing treatment for hepatitis B.

Benitec said that its licence to Uniqure covered the application of ddRNAi to target, and thereby silence, key genes identified as significant therapeutic targets in the treatment of Huntington's disease.

The company said that Uniqure had an option to convert the non-exclusive licence to exclusive, based on achievement of certain pre-clinical milestones, and to acquire additional licences to Benitec's ddRNAi technology for other diseases.

Benitec said the terms were commercial-in-confidence, but they were within the expected guidelines for small biotechnology companies in the early stage of therapeutic development.

Benitec chief executive officer Dr Peter French said that Uniqure was "the first company to gain market approval for a gene therapy product, Glybera, in the West".

"Uniqure has demonstrated its unique ability to take gene therapy-based programs from pre-clinical stages to commercialization and we're confident that they'll achieve a similar outcome in this program," Dr Peter French said.

"This agreement also provides Benitec access to Uniqure's AAV delivery technology, potentially enabling further development of our ddRNAi treatment for hepatitis B," Dr French said.

Uniqure chief executive officer Jorn Aldag said the agreement "gives us certainty around our freedom to utilise ddRNAi for our Huntington's program".

"We look forward to continuing the development of our novel therapeutics for the treatment of Huntington's disease, utilising Benitec's ddRNAi-based gene silencing technology and our proprietary AAV delivery platform," Mr Aldag said

Benitec was unchanged at 1.4 cents.

UNIVERSAL BIOSENSORS

Australian Ethical Smaller Companies Trust has become a substantial shareholder in Universal Biosensors with the acquisition of 8,656,562 shares or 5.02 percent.

Australian Ethical said that it bought shares from September 25, 2012 with the largest single acquisition 351,870 shares for $316,683 or 90 cents a share.

Universal Biosensors fell one cent or 1.1 percent.

GI DYNAMICS

Last night's edition reported an incorrect initial holding in GI Dynamics by M&G Investment Funds.

M&G's correct change of substantial holding in GI Dynamics was from 34,450,520 Chess depositary interests (12.01%) to 37,523,174 CDIs (13.08%).

The sub-editor has had his interest rate cut.

GI Dynamics fell one cent or 1.6 percent to 63 cents.

EASTLAND MEDICAL SYSTEMS

Eastland has appointed chief executive officer Stephen Carter as its executive chairman and chief financial officer Joseph Ohayon as an executive director.
Eastland said Michael Stewart would remain a non-executive director.
The company said that Mr Stewart was appointed a director on June 11, 2009 and had a corporate and management background and was “extensively involved in bilateral donor funded and World Bank co-financed aid projects in under-developed countries”.
Eastland said it would continue to look for an appropriately credentialed and experienced non-executive director.
The company said that as Artimist sub-lingual paediatric malaria project matured it was “looking to broaden our portfolio to provide greater potential return to our shareholders”.
Eastland said that it had assessed opportunities in areas such as cancer, vaccines and devices.
The company said that it had engaged an unnamed European consultant to identify potential opportunities, reviewed other investment opportunities within the pharmaceutical field and we are continuing to assess further projects.
Eastland said Mr Carter had extensive pharmaceutical industry experience and had held senior positions with listed and un-listed public companies including as chairman and managing director.
The company said that Mr Carter had extensive contacts and experience in the financial markets and the pharmaceutical industry and was qualified to lead executive management through the commercialization process.
Eastland said that Mr Ohayon was appointed chief financial officer in July 2010 and in March 2011 he was appointed as company secretary.
The company said that Mr Ohayon had more than 20 years experience in financial roles including 12 years within health-related industries.
Eastland said that Mr Ohayon held a Masters of Business Administration from Murdoch University.
Eastland was up 0.1 cents or 3.6 percent to 2.9 cents.