



Biotech Daily

Friday June 17, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN:**
 - **UNIVERSAL BIOSENSORS UP 10%, QRX DOWN 6%**
- * **IMMUNE SYSTEM MULTIPLE MYELOMA TRIAL: RESPONSE, NO TOXICITY**
- * **CELLESTIS SCHEME BOOKLET: 7c DIVIDEND, ACTION GROUP REBUT**
- * **J&J VERIO GLUCOSE METER RECALL - NO UNIVERSAL BIO IMPACT**
- * **HEALTHLINX NOTE, PLACEMENT, OPTION PAYMENT RATIFICATION EGM**
- * **ROSHI BLUE TAKES 7% OF BLUECHIIP**

MARKET REPORT

The Australian stock market edged up 0.13 percent on Friday June 17, 2011 with the S&P ASX 200 up 5.7 points to 4,484.9 points.

Ten of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and 10 were untraded. All three Big Caps were up.

Universal Biosensors was the best, climbing nine cents or 10 percent to 99 cents with 476,902 shares traded, with Genetic Technologies up 10 percent to 16.5 cents with 458,610 shares traded.

Viralytics was up 5.7 percent; Anteo, Clinuvel, Living Cell, Pharmaxis and Resmed rose more than two cents; with Cochlear, CSL, Mesoblast and Sirtex up one percent or more.

QRX led the falls, down 10 cents or 5.9 percent to \$1.60 with 91,022 shares traded, followed by Circadian down 5.8 percent to 56.5 cents with 3.083 shares traded, Acrux down 5.3 percent to \$3.42 with 1.2 million shares traded and Prana down 5.3 percent to 18 cents with 34,700 traded.

Bionomics, Nanosonics, Optiscan and Tissue Therapies fell four percent or more; Biota, Impedimed and Patrys lost more than three percent; Alchemia and Cellectis shed more than two percent; with Prima down 1.8 percent or more.

IMMUNE SYSTEM THERAPEUTICS

Immune System Therapeutics says it will expand its phase II trial of MDX-1097 for multiple myeloma following a positive response for one of the first patients dosed.

Immune System's chief executive officer Alan Liddle and head of clinical development Dr Roseanne Dunn told Biotech daily that MDX-1097 had achieved the monotherapy response and had "no side effects and no drug related toxicities".

Dr Dunn said current therapies for multiple myeloma had some efficacy but came with significant side effects.

Dr Dunn said the 12-patient, phase I, dose-ranging trial was completed in February 2010 and the dose of 10mg/kg once per week for eight weeks was selected for the phase II trial of 13 patients at Melbourne's Alfred Hospital.

Dr Dunn said the trial protocol included the provision that once one patient responded to treatment the trial would be expanded to 27 patients.

In a media release Immune System said the trial expansion followed a positive review of safety and efficacy data by an independent data monitoring committee of data from the first six patients treated with the new monoclonal antibody therapy.

Immune Systems said the trial's principal investigator was the Alfred Hospital's head of malignant haematology and stem cell transplantation Prof Andrew Spencer.

Immune Systems said MDX-1097 was a genetically engineered antibody that bound to a target protein found on the cell surface of some types of blood cancer.

The company said that it expected the antibody would potentially reduce the number of cancerous cells in multiple myeloma patients by working with the immune system to induce death of multiple myeloma cancer cells.

Mr Liddle said the company was "very excited to have achieved this important milestone towards our goal of developing an effective treatment for patients suffering from this debilitating blood cancer".

"We intend to initiate another hospital site in Australia to accelerate recruitment as soon as possible," Mr Liddle said.

"Simultaneously we are putting in place the appropriate licencing structure to enable the further clinical development and regulatory processes needed to commercialize this promising new medical treatment," Mr Liddle said.

"We are in discussion with a number of global pharmaceutical companies," Mr Liddle said.

Dr Dunn said the responding patient had shown "a very good decrease in blood levels of both of the abnormal or monoclonal proteins produced by the myeloma cells".

"No adverse effects or drug related side effects have been observed in any patients as the antibody only targets and kills the kappa myeloma cells and doesn't bind to any normal cells or tissue," Dr Dunn said.

"The response we are seeing is rare in cancer treatment and an indication that the antibody specifically targets cancer cells and not normal cells," Dr Dunn said.

"Our current phase II trial builds on the results of the phase I trial in 12 patients at the Alfred Hospital which showed the drug was safe and well tolerated and no drug related toxicities were observed," Dr Dunn said.

Immune Systems said multiple myeloma was a debilitating terminal disease, with an estimated patient population of more than 150,000 worldwide.

The company said the disease typically occurred in older patients and was responsible for two percent of all cancer deaths in the US every year.

Immune Systems said it was undertaking additional preclinical work using the same antibody platform technology to target other diseases with major unmet clinical needs.

Immune System Therapeutics is a public unlisted company.

CELLESTIS

The Cellestis scheme booklet says the independent valuation of the company is \$3.00 to \$3.50 a share compared to Qiagen's \$3.55 offer, proposes a special seven cent dividend and rebuts shareholder action group estimates as "optimistic or unreasonable".

Cellestis said that if a special dividend was paid it would be reduced from the \$3.55 cash offer if it was declared and payable before the scheme was implemented.

Cellestis said it had the right to pay a fully-franked special dividend subject to certain conditions, including the receipt of a favorable Australian Taxation Office ruling.

The company said there was no certainty that the ATO would issue a favorable ruling and the exact amount of the special dividend, if any, would be determined at the time of its declaration, after analysis of the company's financial position.

Cellestis said that if the scheme was not implemented, the dividend would not be paid.

The booklet said the independent expert, Deloitte Touche Tohmatsu, assessed the fair market value of a Cellestis Share in the range of \$3.00 to \$3.52 and said the "consideration offered by Qiagen is above the range of our estimate".

"Accordingly it is our opinion that the proposed scheme is fair".

The independent expert concluded that the scheme was fair and reasonable and in the best interests of Cellestis shareholders.

The booklet said the independent expert in a supplementary report considered the Cellestis Shareholder Action Group valuations of \$9.79 (6% discount rate) or \$11.53 (8% discount rate) and said "the discounted cash flow methodology used in the CSAG valuation is not considered to be an appropriate primary valuation methodology for the valuation of Cellestis due to the inherent uncertainties around the key drivers of Cellestis' business, which can lead to a wide range of possible future cash flows and valuation outcomes".

The CSAG valuations are at <http://www.csag-blog.com>.

Deloitte Touche Tohmatsu said the application of the discounted cash flow methodology in the CSAG valuation contained "a number of material assumptions that appear to be optimistic or unreasonable".

"In particular the rate of revenue growth, future operating profit margins and discount rate assumptions that have been applied to future cash flows estimates, in the independent expert's opinion, are either unrealistic or inconsistent with the underlying risk profile of Cellestis," the booklet said.

"The analysis that has been performed by CSAG does not utilise any alternative market based assessments to cross check the conclusions reached by its analysis," the booklet said.

"Upon performing suitable cross checks, the conclusions reached by CSAG imply valuation multiples which are significantly higher than those implied by the historical trading of Cellestis shares as well as being significantly higher than the trading multiples and recent transaction multiples identified by the independent expert in its independent expert's report," the booklet quoted Deloitte Touche Tohmatsu.

"The value of a Cellestis share as determined by CSAG is 340 percent to 360 percent of the recent trading levels of Cellestis with no adequate explanation provided by CSAG," the booklet quoted Deloitte Touche Tohmatsu.

Cellestis said the directors "unanimously recommend that, in the absence of a superior proposal, Cellestis shareholders (other than excluded shareholders) vote in favor of the scheme" and the directors intended to vote all shares they hold or control in favor of the scheme, in the absence of a superior proposal.

The July 20 scheme meeting will be held at the RACV Club, Level 17, 501 Bourke Street, Melbourne, at 1.30pm.

Cellestis fell eight cents or 2.4 percent to \$3.24.

JOHNSON & JOHNSON, UNIVERSAL BIOSENSORS,

Johnson & Johnson Medical has recalled a batch of Lifescan Onetouch Verio blood glucose meters, following error message signals.

The meters were designed by Universal Biosensors under licence to Johnson & Johnson's Lifescan, which produces the meters separately from the Melbourne-based Universal Biosensors test strip manufacturing plant.

Universal Biosensors receives a payment for every test strip used in the meters.

Universal Biosensors chief executive officer Paul Wright told Biotech Daily that the recall would not have a material impact on his company.

In its recall notice, the Australian Therapeutic Goods Administration said the fault was caused by the use of incorrect solder wire causing contamination across the strip port connector pins.

A Johnson & Johnson spokesperson said there was a contaminated component in some meters in a batch of 9,500 meters produced by Johnson & Johnson in Malaysia, between August and December 2010.

Mr Wright said there had been 179 complaints in Australia and seven in the Netherlands. "It's not great, but it's not something that affects us directly or is material to the company," Mr Wright said.

Mr Wright said the Universal Biosensors' test strips were not involved in the recall.

In a media release, Johnson & Johnson said it was aware of "a small number [of] Onetouch Verio blood glucose meters incorrectly producing an 'Error 2' message when testing in conditions of high temperature and/or humidity".

Johnson & Johnson said the error message had "no impact on the accuracy of test results produced by these meters".

"If the meter does not give an error message then the meter is reliable," Johnson & Johnson said.

"The strips and the control test solution used with the meter are NOT affected by this recall," Johnson & Johnson said.

Johnson & Johnson said it would provide a free replacement meter, for any customer whose meter was part of the recall, whether they had an 'Error 2' message or not.

Universal Biosensors closed up nine cents or 10 percent at 99 cents.

HEALTHLINX

Healthlinx shareholders will vote to ratify the convertible note facility with Springtree, renew a 50,000,000 share and option payment and 10,000,000 payment options.

Healthlinx said it had a \$7,239,000 facility with Springtree Special Opportunities Fund of which \$1,930,000 in 20 tranches and under the agreements required shareholder approval for further tranches to be advanced.

The company said it had previously sought shareholder approval for a placement of up to 50,000,000 shares and attaching options and hoped to complete the placement on schedule by July 28, 2011.

Healthlinx said that if it could not be completed by that date it would be prudent to have shareholder approval to extend the approval for a further three months.

The company said its agreement with "US full-service investment bankers" as the placement agents would require the ability to provide unlisted options as part of the fee structure.

The meeting will be held at the Healthlinx offices, 576 Swan Street, Richmond, Victoria on July 19, 2011 at 2pm (AEST).

Healthlinx was up 0.4 cents or 10.8 percent to 4.1 cents.

BLUECHIIP

Roshi Blue has become substantial shareholders in Bluechiip with the acquisition of 5,310,664 shares or 6.78 percent of the company.

The initial substantial shareholder notice signed by director Robert Kampf said Roshi Blue of PO Box 2208, North Brighton, Victoria, was the registered holder.

The notice said the shares were acquired for cash and non-cash.

Bluechiip recently listed on the ASX at 25 cents a share to develop its bio-tracking device (BD: Jun 9, 2011).

Bluechiip fell four cents or 21.05 percent to 15 cents.