

# Biotech Daily

Tuesday October 11, 2011

Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: ALLIED HEALTH UP 24%; ANTISENSE DOWN 11%
- \* ALLIED JUMPS 48.5% ON 100% HSV-2 DNA VACCINE EFFICACY IN MICE
- \* ANTISENSE COMPLETES PHASE I ATL1103 DOSING
- \* UNIVERSAL BIOSENSORS \$4.5m J&J BLOOD GLUCOSE PROJECT
- \* HUNTER IMMUNOLOGY TO TAKE PROBIOMICS TO BIOXYNE
- \* HEALTHLINX OVPLEX TRIAL 'MORE SAMPLES, BETTER RESULT'
- \* AUSBIOTECH READY FOR 2011 CONFERENCE
- \* BIO-MELBOURNE BREAKFASTS ON MOVEMBER

## MARKET REPORT

The Australian stock market was up 0.63 percent on Tuesday October 11, 2011 with the S&P ASX 200 up 26.6 points to 4,227.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and seven were untraded.

Allied Health was the best, climbing 48.5 percent to 4.9 cents and closing up 0.8 cents or 24.2 percent at 4.1 cents with 7.9 million shares traded.

Patrys and Prana climbed more than nine percent; Mesoblast rose 6.2 percent; Circadian and LBT were up five percent or more; Alchemia and Tissue Therapies were up more than four percent; Starpharma was up three percent; Acrux rose 2.5 percent; with Cochlear, Phylogica and Reva up more than one percent.

Antisense led the falls, down 0.1 cents or 11.1 percent to 0.8 cents with 7.4 million shares traded, followed by Cellmid down 10.5 percent to 1.7 cents with 301,069 shares traded.

Living Cell lost 6.25 percent; Clinuvel and Phosphagenics shed two percent or more; Anteo, Optiscan and Pharmaxis were down more than one percent; with CSL, Impedimed, Nanosonics and Resmed down by less than one percent.

### ALLIED HEALTH GROUP

Allied Health opened up 48.5 percent to 4.9 cents on news that its Coridon subsidiary's DNA vaccine for herpes simplex virus 2 had 100 percent efficacy in US pre-clinical trials. Allied chief executive officer Lee Rodne told Biotech Daily that the mouse data was a follow-up of earlier studies and was presented at the Vaccine and ISV Annual Global Congress in Seattle last week by the University of Washington's Prof David Koelle. Mr Rodne said he could not disclose how much of Coridon was held by Allied but said his company had the right to acquire up to 55 percent of Coridon and the pre-clinical trial results triggered the right to increase its current holding.

"These data provide fantastic validation to the Coridon platform which could be applied to a number of infectious diseases," Mr Rodne said in an Allied media release.

Coridon is co-owned with Queensland University's Uniquest, inventor Prof Ian Frazer and three other scientists (BD: May 19, 2011).

Allied said that Coridon collaborated with Prof David Koelle and his colleagues testing a number of different formulations of its prototype DNA vaccine and the formulations "proved 100 percent effective" at protecting mice against herpes simplex virus 2 (HSV-2) infection, confirming an earlier University of Washington study which demonstrated 90-100 percent protection against infection.

Allied said it would provide additional funding to Coridon to begin manufacturing and undertake pre-clinical safety studies before moving to a phase I human trial.

Coridon chairman Prof Ian Frazer said he expected pivotal data showing the vaccine produced similar responses in the clinic to those in the animal trials within 12 months. Coridon is developing DNA vaccines for the prevention and treatment for a range of infectious diseases and cancers in humans, using its DNA vaccine technologies which unlike conventional vaccines offer both preventative and therapeutic value.

Allied said that according to the US Centers for Disease Control, genital herpes affects more than one in six Americans between ages 14 and 49, often resulting in recurrent painful sores in the genital area.

Allied said that HSV-2 could have serious health implications for babies born to infected women and that it was believed to aid in the transmission of HIV.

Allied closed up 0.8 cents or 24.2 percent at 4.1 cents with 7.9 million shares traded.

## **ANTISENSE THERAPEUTICS**

Antisense says subject dosing has been completed in its randomized, placebo-controlled, double blind study phase I trial of ATL1103 targeting the growth hormone receptor. Antisense said the ATL1103 phase I trial was of single ascending doses and multiple doses of ATL1103 in healthy adult male subjects and the multiple dosing phase of the trial concluded with no serious adverse events reported over the 21-day dosing period. The company said the subjects were in the monitoring phase of the study and would be assessed for potential residual effects of the dosing phase.

Antisense said the trial remained blinded until monitoring and laboratory testing was completed and the database was locked for analysis.

Antisense said the results were expected by the end of 2011.

The company said ATL1103 was designed to block the expression of the growth hormone receptor to reduce levels of the hormone insulin-like growth factor-I (IGF-I) in blood, the therapeutic endpoint in treating the growth disorder acromegaly.

Antisense said that reducing the effects of IGF-I had a potential role in the treatment of diabetic retinopathy, diabetic nephropathy and some cancers.

Antisense fell 0.1 cents or 11.1 percent to 0.8 cents with 7.4 million shares traded.

## **UNIVERSAL BIOSENSORS**

Universal Biosensors says it has a new \$US4.5 million research and development project for Johnson & Johnson Lifescan affiliate, Cilag GmbH International.

Universal Biosensors said that following preliminary scoping work earlier this year, it would conduct a research and development feasibility study for a blood glucose product, which was expected to take about 12 months.

The company said the \$US4.5 million was dependent on achieving set milestones. Universal Biosensors said that commercialized test strips resulting from the feasibility work would have an increased quarterly service fee payable by Cilag, for a period of time. In a media release Universal Biosensors chief executive officer Paul Wright said that having developed the One Touch Verio blood glucose test strip for Lifescan, the company looked forward to working closely with the Lifescan and Cilag ..."and reaffirming our unique innovation capabilities in the field of diabetes".

Mr Wright told Biotech Daily that glucose applications would belong to Lifescan, but if the test produced aspects outside glucose Universal Biosensors could use those applications for non-glucose related products.

"It cements the ongoing relationship with Lifescan and our role as an innovator for them in the field of diabetes," Mr Wright said.

Universal Biosensors is separately developing point-of-care coagulation tests for Siemens Healthcare Diagnostics (BD: Sep 9, 2011).

Universal Biosensors was unchanged at 90 cents.

## HUNTER IMMUNOLOGY, PROBIOMICS

Hunter Immunology and Probiomics have agreed to merge with the resulting diverse product company to be renamed Bioxyne.

Hunter Immunology chief executive officer David Radford told Biotech Daily that the backdoor listing through Probiomics would see an expansion of the listed company's probiotic products and there were talks with a potential global partner.

Mr Radford said the new entity would establish higher value over-the-counter products and distribution of nutritional products and additives.

"We will acquire a distribution company for Australia by the end of 2011 and hope to have the ASX merger process completed early in 2012, pending shareholder approvals," Mr Radford said.

Mr Radford said his company's 320-patient, phase IIb HI-164 Haemophilus influenzae vaccine for chronic obstructive pulmonary disease (COPD) had early indications of safety with results expected by April 2012.

Last year, Hunter reported its 40-patient trial of HI-164OV (oral vaccine) for COPD had reduced hospital admissions by 90 percent (BD: Apr 22, 2010).

In a media release Probiomics said it would make an off-market bid for all Hunter Immunology shares, subject to conditions including a minimum of 90 percent acceptances of Hunter Immunology shares, Probiomics shareholder approval, a successful public offer, re-admission of Probiomics to the official list and no superior offer being made.

Probiomics said the implied valuation of its shares for the merger was 1.1 cents a share and with nine Probiomics shares for each Hunter share, implied a value of \$29.74 million for Hunter Immunology.

Probiomics said it would seek to raise up to \$3 million and all post-takeover Probiomics shares would be consolidated on a one-for-20 basis.

Hunter Immunology is a public unlisted company.

Probiomics extended its trading halt to a suspension, last trading at 0.6 cents.

### HEALTHLINX

Healthlinx says the increased number of samples analyzed in its trial of the Ovplex ovarian cancer diagnostic shows increasing accuracy compared to CA-125.

Healthlinx said that 740 samples of the total of 1150 samples had been collected in the second part of its second trial of the five-biomarker panel which includes CA-125 compared to the current industry standard of CA-125 alone.

Healthlinx managing director Nick Gatsios told Biotech Daily that 485 samples had been collected in the first part of the study with a further 21 patient samples included that were categorized as 'borderline' and previously excluded (BD: Feb 15, 2011).

In a media release today, Healthlinx said that part two of the study consisted of an additional 234 samples collected from symptomatic women presenting to specialist clinics in both Australia and the UK.

The company said that collaborators at Brisbane's Mater Hospital, led by principal investigator Prof Lewis Perrin and the Essex, UK Southend Hospital Network led by Dr Khalil Razvi were responsible for overseeing recruitment and collection of samples. Healthlinx said the complete sample set to date comprised 222 women with malignant epithelial ovarian cancer, 53 women with confirmed borderline ovarian tumors, 223 women with benign gynecological conditions and 244 apparently healthy controls. The company said that the first Ovplex trial was conducted using only malignant ovarian cancer patient samples and normal controls.

Healthlinx said the present data set demonstrated a highly statistical significant increase in diagnostic performance of the Ovplex multi-marker test over CA125 alone as determined by "the area under the curve" of 94.9 for Ovplex compared to 91.9 for CA-125 (p < 0.007). The company said the new data confirmed that the performance of the Ovplex test was the same, if not better, in a larger and independent sample set, indicating the consistent and robust performance of the Ovplex test.

Healthlinx said that all statistical analyses were conducted independently by Emphron Informatics using multiple methodologies including comparisons of the area under the receiver operating characteristic curve.

The company said that statistical modeling using more complex sample sets that included all 742 samples (control and benign compared with malignant and borderline ovarian cancer samples) demonstrated that Ovplex maintained a significant diagnostic advantage over CA125 as determined by the area under the curve with 88.4 for Ovplex compared to 84.3 for CA-125 (p < 0.001).

Healthlinx said that 17 malignant ovarian cancer patients missed by CA125 were identified by Ovplex and, of these, eight were stage I and II, two were stage III and seven were of unknown stage.

Healthlinx chief scientific officer Dr Dominic Autelitano said the comparison was "particularly important since it represents a clinically relevant sample cohort that defines the proposed diagnostic label use of the Ovplex test".

Dr Autelitano said the data was "a significant advance in the demonstrating the performance of the Ovplex test".

"Whichever way you analyze these data, Ovplex clearly outperforms CA125 alone," Dr Autelitano said. "Ovplex continues to deliver outstanding results even with the inclusion of benign and borderline patients."

"Importantly, Ovplex identified seven early stage ovarian cancer patients that would otherwise have been missed by using CA125 alone," Dr Autelitano said.

Healthlinx said Ovarian cancer was the most lethal of the reproductive tract cancers with more than 240,000 new cases of ovarian cancer diagnosed each year.

Healthlinx was unchanged at 1.7 cents with 1.7 million shares traded.

### **AUSBIOTECH**

Ausbiotech says its 2011 conference in Adelaide, October 16-19, 2011 will close with the Investment Summit on October 19, 2011.

Ausbiotech said the Summit was "the largest life sciences meeting of its kind in the southern hemisphere and the major investment event for Australia and the Asia-Pacific region".

The industry organization said that more than 1,000 delegates would attend the annual conference with about 150 speakers scheduled to address meetings and plenary sessions over the four day conference.

Ausbiotech said speakers on the program included London-based Centreview Partners managing director Dr Cathal O'Reilly, Amgen chief medical officer Dr Willard Dere and Janssen chairman Dr Paul Stoffels

An Ausbiotech media release said Blueprint Life Sciences managing partner Hershel Berry would chair a forum entitled 'International Investors Unplugged' with participation from Venbio's Dr William Shen, Aisling Capital's Dr Anthony Sun, Medimmune Ventures' Dr Ron Laufer, Biotechnology Value Fund's Joe Sum, Scientia Capital's Lawrence Gozlan and Cowen Healthcare Royalty Partners' Clarke Futch.

The media release said that the Business Matching Program had opened for requests from delegates.

Ausbiotech said the program was "a free world-class service ... that each year facilitates more than 1,000 meeting matches.

The media release said that the Prof Nancy Millis Oration would be delivered by Flinders University professor of cancer research Prof Ross McKinnon, who will speak on the translation of health discovery into clinical applications from an Australian perspective. For more information go to: www.ausbiotech2011.com.au.

#### **BIO-MELBOURNE NETWORK**

The Bio-Melbourne Network says Movember Foundation global research program manager Dr Mark Buzza is the guest speaker at the November 8, 2011 Bio-Breakfast. Bio-Melbourne chief executive officer Michelle Gallaher said that it "since its foundation in 2003 the Movember Foundation has raised \$178 million".

"With significant funds being used to address men's health and disease areas, there is more to the Movember Foundation than just growing a moustache once a year," Ms Gallaher said.

The Bio-Melbourne Network said Dr Buzza would discuss the Movember Global Action Plan, which was a collaborative research program investigating prostate cancer biomarkers.

The Network said the initiative aimed to answer key clinical questions to better predict aggressive prostate cancer, characterize metastatic disease and treatment resistance by identifying the clinical biomarkers involved.

The November 8 Bio-Breakfast will be held at the Australian Centre for the Moving Image, Federation Square, Melbourne, with registration from 7:15am.

For more information go to: <a href="http://www.biomelbourne.org/events/view/208">http://www.biomelbourne.org/events/view/208</a>.