Biotech Daily

Friday June 8, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CELLMID UP 12.5%, USCOM, PRIMA DOWN 13%**

*** UNIVERSAL BIOSENSORS EARNS SIEMENS $1.5m TEST MILESTONE**

*** MESOBLAST DENTAL STEM CELLS FOR NEURO DISEASES**

*** UNI OF NSW HEALTH SCIENCE ALLIANCE**

*** CYCLOPHARM COMPLETES SHARE CONSOLIDATION; RETURNS TO CYC**

*** FURTHER DATA CONFIRMS PHARMAXIS BRONCHITOL CF EFFICACY**

*** HEALTH CANADA APPROVES NEW SUNSHINE HEART PUMP DRIVER**

*** PRIMA CLOSES 2 PROJECTS; FOCUS ON CVAC FOR OVARIAN CANCER**

*** NEUREN CEO LARRY GLASS ELECTED M-D, DR GRAEME HOWIE GOES**

MARKET REPORT

The Australian stock market retreated 1.09 percent on Friday June 8, 2012 with the S&P ASX 200 down 44.9 points to 4,063.7 points.

Ten of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and eight were untraded. All three Big Caps were down.

Cellmid was the best, up 0.2 cents or 12.5 percent to 1.8 cents with 6.4 million shares traded.

Phylogica climbed 8.9 percent; Avita was up 7.7 percent; Universal Biosensors was up 6.7 percent; Psivida and Tissue Therapies rose more than two percent; Alchemia and Sirtex were up one percent or more; with Heartware and QRX up by less than one percent.

Uscom led the falls, down 1.1 cents or 13.75 percent to 6.9 cents with 4,000 shares traded, followed by Prima down 13.3 percent to 13 cents with 13.9 million shares traded.

Genetic Technologies lost 10.7 percent; Allied Health and Optiscan fell more than nine percent; Ellex was down 8.8 percent; Phosphagenics was down 6.25 percent; Bionomics fell 4.7 percent; Mesoblast, Prima and Starpharma shed more than two percent; Cochlear and Reva were down more than one percent; with Acrux, Biota, Clinuvel, CSL, Pharmaxis and Resmed down by less than one percent.

UNIVERSAL BIOSENSORS

Universal Biosensors has earned $US1.5 million from Siemens Healthcare Diagnostics for work on handheld analyzers for point-of-care coagulation testing.

Universal Biosensors said it had delivered on its first developmental milestone in its collaboration with Siemens, which related to proof-of-technical-feasibility of a new test strip, on-schedule and on-budget.

The company said that the $US1.5 million payment brought the total payments from Siemens to $US4.5 million.

Universal Biosensors said that under the September 2011 agreement, it would develop a range of test strips and reader products in collaboration with and exclusively for Siemens, which would contribute to development costs through the $US3 million up-front fee as well as a series of six milestone payments.

The company said the first product was expected to be launched in 2013 and was a version of Universal Biosensors' point-of-care prothrombin time-international normalized ratio (PT-INR) test, to monitor the application of the anti-coagulant, Warfarin.

Universal Biosensors said the test strip had passed technical feasibility and would be the basis of a product to be commercialized by Siemens following the launch of the PT-INR test.

Universal Biosensors chief executive officer Paul Wright said that delivering on "this first, challenging milestone on-time and on-budget is an important step forward in our collaboration with Siemens and demonstrates the strength of our research and development capabilities".

"The point-of-care coagulation testing market is large and growing," Mr Wright said.

"Our technology is breaking new ground in this space and Siemens is the perfect partner organization to commercialize coagulation products in this global market," Mr Wright said.

Universal Biosensors said that point-of-care coagulation testing was estimated to be worth more than $US1 billion a year and was growing at more than 10 percent a year.

Universal Biosensors was up four cents or 6.7 percent to 64 cents.

MESOBLAST

Mesoblast's plans to develop allogeneic, or off-the-shelf, adult dental pulp stem cells for stroke, spinal cord injury, Parkinson's and Huntington's diseases.

In a media release Mesoblast said that chief executive Prof Silviu Itescu discussed the plans to develop adult stem cell therapies for neurodegenerative diseases at the Jefferies Global Healthcare Conference in New York.

Mesoblast said that it was in a strategic alliance with Israel's Teva Pharmaceutical Industries in the fields of neurologic and cardiovascular diseases and had exclusive worldwide commercial rights to granted composition of matter patents covering dental pulp stem cells, which are STRO-1 positive mesenchymal precursor cells of neural crest origin.

The company said that the cells produced significantly greater levels of neurotrophic factors and were significantly more effective than other adult stem cell types for neural differentiation and repair of various neural cells and tissues.

Mesoblast said that recent published reports had shown that dental pulp stem cells could be effective for protection and repair of neural tissue after spinal cord injury and stroke.

The company said that Huntington's disease could provide an opportunity for accelerated dental pulp stem cells market entry.

Prof Itescu said that US and European regulators agreed on the design and the primary and secondary endpoints for the planned phase III congestive heart failure trial.

Mesoblast fell 15 cents or 2.3 percent to $6.35.

UNIVERSITY OF NEW SOUTH WALES

The University of New South Wales has created the Health-Science Alliance to integrate the research, education, training and clinical expertise of its member organizations.
The University of New South Wales' Faculty of Medicine's deputy dean Prof Terry Campbell said the Health-Science Alliance was "Australia's first academic health science centre".
"It's a unique alliance of the hospitals, universities, research institutes and independent researchers on the Randwick campus of UNSW and its teaching hospitals," Prof Campbell said.
Prof. Campbell said the name derived from correspondence from Prof Howard Florey while on his quest to the US to produce penicillin in 1941 and the Alliance logo was in Prof Florey's handwriting.
The chairman of the Health-Science Alliance Peter Joseph said "our simple insignia symbolizes a hands-on, no nonsense, sleeves rolled up approach to collaboration".
"At this stage, 12 independent entities make up the Health-Science Alliance collaborating with each other as well as with like-minded entities throughout Australia and the world," Mr Joseph said.
The Alliance said it member institutions were the Prince of Wales Hospital; the Royal Hospital for Women; Sydney Children's Hospitals, Randwick; Prince of Wales Private Hospital; Children's Cancer Institute Australia; Neuroscience Research Australia; Black Dog Institute; Eastern Heart Clinic; UNSW Medicine; the University of New South Wales; and the University of Technology Sydney.
Prince of Wales Hospital clinical school director Prof Robyn Ward said the Health-Science Alliance would "unite the three areas critical to improving outcomes for patients and the community", namely teaching, research and health care.
"It means a new way of thinking in healthcare - a structured cohesive effort never before seen on such a scale in this country," Prof Campbell said.
"With the creation of this Alliance we are embarking on a journey whereby all employees are part of a Centre which uncompromisingly pursues excellence: top to bottom, side to side," Prof Campbell said.
"The Centre takes advantage of a location, Randwick, where three major hospitals and four medical research institutes co-exist with a university medical school and biological sciences facilities," Mr Joseph said.
"The Alliance will encourage a cultural shift in all areas of scientific and medical practice as it introduces new ways of approaching and solving medical problems," Mr Joseph said.
"Finding answers and advancing them to the clinic and applying them to patients must become a smoother, faster process," Prof Campbell said.
"By speeding up and filling the gaps between the laboratory bench-to-bedside and bedside-to-population, approach it can transform the way medicine is practiced in this country for the benefit of all," Prof Campbell said.
"Ultimately it translates to better and more efficient healthcare," Prof Campbell said.

CYCLOPHARM

Cyclopharm says new holding statements have been dispatched, completing to five-to-one share capital consolidation.
Cyclopharm said that post-consolidation it had 44,715,882 fully paid ordinary shares on issue and trading on a normal settlement basis under the code CYC would resume on June 12, 2012.
Cyclopharm was unchanged at 15 cents.

PHARMAXIS

Pharmaxis says that a new analysis of its two phase III clinical studies of Bronchitol shows positive trends in reducing exacerbations in all age sub groups of cystic fibrosis patients.

Pharmaxis said the analysis focused on adult patients and was presented at the European Cystic Fibrosis Meeting in Ireland, coinciding with the commercial launch of Bronchitol in the UK and Germany.

The company said that the two phase III studies had 341 adult patients and their results were broadly consistent with those from the overall population of 600 patients which included adolescents and children.

Pharmaxis said that those adult patients who showed an increase in lung function on Bronchitol had 59 percent fewer exacerbations than patients who showed no improvement ($p = 0.03$).

The company said that exacerbation incidence was reduced by 29 percent in the overall population ($p = 0.039$) and there were consistent improvements in all age groups with a non-significant 24 percent reduction in adults.

Pharmaxis said that sputum weight in adult patients was significantly increased at both six and 14 weeks and lung function in adults showed significant improvements over the six months of the study and were sustained out to 12 months.

The company said that for adults, there was no increase in treatment burden after taking Bronchitol for six months.

Pharmaxis said that exacerbations in cystic fibrosis patients were a distinct worsening of symptoms and the most common reason for hospitalization.

The company said that the exacerbations recorded in the Bronchitol studies were serious events that all necessitated the use of intra-venous antibiotics.

Principal investigation, the University of Washington's Prof Moira Aitken said there was "a significant need for new treatments in cystic fibrosis and the results from the Bronchitol phase III studies suggest this is a very useful drug".

"These trials clearly demonstrate that Bronchitol's action in increasing mucociliary clearance augments other chronic therapies, improves lung function and reduces acute pulmonary exacerbations," Prof Aitken said.

Pharmaxis said the European Cystic Fibrosis Conference was attended by clinicians, healthcare professionals and patient organizations and its Bronchitol featured in four posters, oral presentations and a dedicated symposium.

Pharmaxis chief executive officer Dr Alan Robertson said the company was engaged with cystic fibrosis centres across Europe and the clinical responses possible with Bronchitol had been well received by both patients and clinicians.

"In the six month phase III studies, 45 percent of patients had an improvement in [forced expiratory volume for one second] relative-percent-predicted of five percent or more above baseline and 29 percent of participants improved by 10 percent or more," Dr Robertson said.

"These results suggest Bronchitol is a significant drug for the [cystic fibrosis] community," Dr Robertson said.

"At the same time, other clinical benefits with Bronchitol are being explored and, in an early research investigation presented for the first time at the European meeting, Bronchitol has been shown to increase the potency of tobramycin to clear pseudomonas infections," Dr Robertson said.

"While still at the investigational stage, these results hold out exciting possibilities for the future," Dr Robertson said.

Pharmaxis fell one cent or 0.9 percent to $1.09.

SUNSHINE HEART

Sunshine Heart says Health Canada has approved its next generation C-Pulse heart assist system driver in clinical studies at Royal Victoria Hospital in Barrie, Ontario.
Sunshine Heart said the driver was designed to provide heart failure patients with enhanced patient comfort and performance.
The company said the new C-Pulse driver was a single unit half the size, lighter and quieter than the first generation technology, with a number of software enhancements.
Sunshine Heart said the C-Pulse system was in an investigational study at Royal Victoria Hospital and was based on balloon counter-pulsation technology for the treatment of patients with Class III and ambulatory Class IV heart failure.
The company said that the prospective study was designed to evaluate the safety and performance of the C-Pulse system as a treatment for patients with moderate to severe heart failure and to date, four patients had been implanted with the initial C-Pulse system.
Sunshine Heart said it had approval to expand the trial to 20 patients and all participants would receive the new driver, which would be used in ongoing and future clinical studies.
Sunshine Heart chief executive officer Dave Rosa said the company enhanced the driver based on results from the feasibility trial and feedback from physicians and patients.
“With the reduced size, weight and noise reduction, we expect improvements in patient quality of life due to enhanced comfort and performance,” Mr Rosa said.
Sunshine Heart said the C-Pulse driver inflated and deflated the balloon which was secured by a cuff around the outside of the ascending aorta, with cuff and heart signal sensing wires attached to the driver, which inflated and deflated the balloon in sequence with the electrocardiogram signal to assist heart function and pumping capacity.
The company said the balloon deflected the aorta, which was intended to minimize aortic wall strain and maximize blood volume displacement per beat.
Sunshine Heart was untraded at 2.3 cents.

PRIMA BIOMED

Prima says it will wind down its Dubai business activities and has terminated its Netherlands preclinical development of the Cripto-1 antibody program
Prima said the Dubai business was based on a pilot ovarian cancer CVac program, with the operating cost underwritten by revenues earned from providing non-CVac-related blood separation or apheresis services at the City Hospital but had been closed “due to regulatory delays and logistical challenges that would make it difficult to treat patients and achieve profitability in a reasonable amount of time”.
The company said the decision would allow the company to refocus on clinical development of CVac in larger markets including the US, Europe, and Australia.
Prima chief executive officer-designate Matthew Lehman said the company had tried to establish a successful CVac and apheresis program in Dubai, but assumptions about revenue and the timeline for CVac exported to Dubai were “optimistic”.
Prima said it began a collaboration with the Netherlands-based Bioceros BV in 2010 to develop functional antibodies against Cripto-1 and while the antibodies demonstrated strong binding capacity, they did not demonstrate tumor cell killing ability.
Prima said that further development of the program would require re-generating new antibodies or finding a cytotoxic compound to combine with the Cripto-1 antibodies and neither approach fitted the company’s strategic vision.
Mr Lehman said that “prompt termination of unsuccessful projects is an important part of rational product development”.
Prima fell two cents or 13.3 percent to 13 cents with 13.9 million shares traded.

NEUREN PHARMACEUTICAL

Neuren has elected Larry Glass as managing director while director Dr Graeme Howie has retired by rotation and chosen not to stand for re-election.
Neuren said that Dr Howie had been a director since February 2005.
The annual general meeting was held on May 31, 2012.
Neuren was unchanged at 2.5 cents with 10.5 million shares traded.