Biotech Daily

Thursday September 4, 2008

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECHS UP: SUNSHINE UP 9%, ACRUX DOWN 9%**

*** PHYLOGICA, CAMBRIDGE PARTNER ON CANCER DRUGS**

*** ANADIS DEVELOPING ADJUNCTIVE THERAPY FOR HIV/AIDS**

*** FLUOROTECHNICS IPO TO RAISE $12m TO EXPAND PRODUCTION**

*** US ARMY PROVIDES $US5.5m MORE FOR NEUREN PHASE II TRIAL**

*** PHARMAXIS BEGINS SECOND PIVOTAL CYSTIC FIBROSIS TRIAL**

*** CYTOPIA BEGINS PHASE Ib/II BRAIN CANCER TRIAL**

*** PROGEN LOSES 25% OF STAFF, DIRECTOR PROF JOHN ZALCBERG**

*** VICTORIA FUNDS $26m FOR RESEARCH OPERATIONS**

*** VICTORIA, NSW PROVIDE $500k FOR STEM CELL RESEARCH**

*** VIRALYTICS APPOINTS PAUL HOPPER DIRECTOR**

*** HEALTHLINX APPOINTS DR DOMINIC AUTELITANO CSO**

MARKET REPORT

The Australian stock market fell 1.6 percent on Thursday September 4, 2008 with the All Ordinaries down 79.6 points to 5,050.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and seven were untraded.

Sunshine Heart was best, up 0.5 cents or 9.09 percent to six cents on small volumes, followed by Phylogica up 7.5 percent to 8.6 cents and Polartechnics up 7.14 percent to 10.5 cents. Prana climbed 6.98 percent; Cytopia was up 4.76 percent; Heartware, Novogen and Pharmaxis were up more than three percent; Progen, Sirtex and Ventracor rose more than two percent; with Biota, Clinuvel, Cochlear, Neuren and Starpharma up more than one percent.

Acrux led the falls, down 10 cents or 8.7 percent to $1.05 on small volumes, followed by Alchemia down 7.25 percent to 32 cents and Chemgenex down 6.06 percent to 93 cents. Antisense, Cellestis and Peplin fell more than five percent; Circadian, CSL, Mesoblast, Phosphagenics and Universal Biosensors shed more than two percent; with Avexa, Psivida and Resmed down more than one percent.

PHYLOGICA

Phylogica says it has signed an agreement with Cambridge University researchers to develop and market new cancer drugs.
Phylogica said the joint agreement was with the Medical Research Council and Cambridge University's Cambridge Molecular Therapeutics Programme.
The company said the first stage of the collaboration would be the translation of Phylogica's exclusive Phylomer peptide library into a new format, to increase the methods of screening to identify potential drug candidates.
Phylogica said its proprietary Phylomer libraries were collections of hundreds of millions of Phylomer peptides, "a rich source of drug leads for a broad range of disease targets".
Phylogica said Phylomer peptides were stable fragments of naturally-occurring proteins which bind tightly and specifically to disease targets.
Phylogica said the program would be headed by Prof Ashok Venkitaraman and Dr Grahame McKenzie working with scientists in the Cambridge Molecular Therapeutics Program and the MRC Cancer Cell Unit at the Hutchison MRC Research Centre.
Prof Venkitaraman said the Phylomer libraries were a unique asset containing "more than 260 million Phylomer peptides".
Phylogica's executive chairman Aki von Roy said the collaboration highlighted interest in the Phylomer technology and added value to the technology for potential partners.
"The expansion into cancer through a world-leading collaborator opens up an even bigger potential market, highlighting the enormous breadth of application of the Phylomer technology for diseases other than the anti-inflammatory field," Mr von Roy said.
Phylogica was up 0.6 cents or 7.5 percent to 8.6 cents.

ANADIS

Anadis says its Biogard for gastrointestinal and immune system health, may be an adjunctive therapy for HIV/AIDS patients.
Anadis said the product was intended to improve the efficacy of immune system repair during highly active antiretroviral treatment.
The company said the gastrointestinal immune system was important in the progression of HIV-related immune depletion and local gastrointestinal symptoms.
Anadis said the market for Biogard included more than one million patients in the US, two million in Europe and Central Asia and more than 30 million worldwide.
The company said Biogard would be launched in 2009 following a phase IIIb/IV multi-site clinical trial beginning in 2008, which was in "an advanced stage of planning".
Biogard would be marketed as an over-the-counter medical food.
Anadis said Biogard's active ingredient was an oral formulation of antigen-targeted bovine colostrum powder from cows vaccinated for routine pathogens and vaccinated with an Anadis vaccine with lipopolysaccarides found in gram negative bacterial cell walls that were implicated as key drivers of AIDS pathogenesis.
Anadis said data supporting the work was presented at the Australian Society for Microbiology meeting by scientists from Melbourne's Royal Children's Hospital and the Department of Microbiology and Immunology at the University of Melbourne.
Anadis said it was in advanced discussion with "a major AIDS research institution" to test Biogard's efficacy in a multi-site, randomized, double-blind, placebo-controlled study to measure the effect of combination antiretroviral therapy intensification with Biogard on CD4+ outcomes in HIV1 infected individuals with suboptimal CD4 response to therapy despite prolonged virologic suppression.
Anadis was unchanged at 6.5 cents.

FLUOROTECHNICS

Fluorotechnics hopes to raise up to $12 million in an initial public offer to ramp up production of its protein detection and analysis equipment and list on the ASX.

Fluorotechnics was spun-out of Macquarie University by chief executive officer Prof Duncan Veal in 2002.

It acquired German-based Elektrophorese-Technik in November 2007 and is in the process of acquiring the San Francisco based The Gel Company.

In an investor briefing in Melbourne, Prof Veal said both companies were highly synergistic with Fluorotechnics.

Elektrophorese-Technik develops and manufactures high-end electrophoresis consumables including specialized high value gels and instrumentation for DNA and protein electrophoresis.

The Sydney-based Fluortechnics produces and sells high value consumables for protein research and has 200 customers of which “98 percent” are outside Australia, evenly split between Europe and the US.

Prof Veal said the two acquisitions gave it experienced and well connected staff on both continents and The Gel Co acquisition brought with it a further 500 customers.

Prof Veal said that his company’s plastic mounted gel plates were superior to the existing glass competitors in terms of health and safety, storage and disposal.

He said the key intellectual property was “discovered by accident” in 1994 while researchers at Macquarie University were looking for a fluorescent molecule.

“A chance fungal molecule landed on an agar plate,” he said.

The molecule from the epicocconone family was kept quiet, researched and the first patent was obtained by the University. Prof Veal said Fluorotechnics had acquired the intellectual property from the University without any trailing licence fees or royalties and the University remained a six percent equity holder.

He said the company acquired Elektrophorese-Technik primarily for stock and The Gel Co would also be acquired primarily for stock.

Elektrophorese-Technik’s owners hold eight percent of the company with the right to up to a further 10 percent if sales of gels over three years increase to more than $50 million.

He said the Fluorotechnics board and management currently hold 40 percent of shares.

Prof Veal said the technology was so far advanced over its competitors that one existing customer said Fluorotechnics had “converted it from a $100,000 a year research and development company to a potentially $3 million a year diagnostics company”.

The company plans to bring 20 new products to the market in the next three years. Unlike many other biotechnology companies Fluorotechnics does not require FDA approvals to sell its consumables and is already generating revenues.

Prof Veal said the IPO was not underwritten but there was significant institutional support.

Fluorotechnics board is chaired by co-founder Rick Taylor a tax partner for more than 20 years and leader of Deloitte’s private equity team.

The former chief executive officer of the Coles Group John Fletcher was one of the first investors in the company in 2002 and joined the board in March 2008.

Other directors include former Stratagene vice president David Weber, former Macquarie University deputy vice chancellor Prof Peter Bergquist, Prof Veal and former GE Healthcare global strategic marketing director, Gunter Thesseling.

Fluorotechnics’ IPO at $1 a share is due to open on September 10 and close on October 10, 2008.

When listed, Fluorotechnics will have 26-28 million shares with a market capitalization of $26-28 million.

BBY is the float’s lead manager and the prospectus is at http://www.fluorotechnics.com.

NEUREN

Neuren says the US Army has put an additional $US5.5 million into its planned phase II clinical trial of NNZ-2566 for traumatic brain injury.

With the US Army investment of $US4 million to cover direct costs of the study Neuren said this gave a total commitment of $US9.5 million.

Neuren and the US Army will initiate the phase II trial of NNZ-2566 in 200 moderate to severe traumatic brain injury patients in early 2009 with results expected in 2010.

Neuren said NNZ-2566 was a synthetic analogue of Glypromate, a naturally-occurring neuropeptide derived from insulin-like growth factor 1 (IGF-1), which was originally being trialed to reduce cognitive impairment in patients undergoing cardiac surgery with cardiopulmonary bypass.

Neuren said the neuroprotective properties of NNZ-2566 are believed to derive from inhibition of inflammatory and apoptotic (cell death) processes that can result from traumatic brain injury, possibly by preventing activation of microglia, part of the cellular inflammatory response to brain injury.

As a result of the funding announcement Neuren said it had extended the share purchase plan closing date to September 16, 2008 (see Biotech Daily; August 6, 2008).

Neuren was up 0.1 cents or 1.28 percent to 7.9 cents.

PHARMAXIS

Pharmaxis says it has started its second pivotal phase III clinical trial evaluating Bronchitol for cystic fibrosis.

Pharmaxis said the phase III trial was being conducted in 41 hospitals across North America, Argentina and Germany and followed the first phase III trial involving 325 subjects.

Pharmaxis chief executive officer Dr Alan Robertson said Bronchitol had been awarded fast-track status in the US with orphan drug designation in both the US and EU.

“We look forward to bringing Bronchitol to the international cystic fibrosis community as rapidly as we can,” Dr Robertson said.

The company said the phase III clinical trial was designed to include a 26-week efficacy treatment period, followed by a 26-week safety period.

The efficacy component of the trial was a randomized, double-blind investigation of Bronchitol twice daily in approximately 300 patients with cystic fibrosis.

The company said that the trial was enrolling cystic fibrosis patients aged six years and older.

Pharmaxis said participants would be assessed for improvements in lung function, infectious episodes, antibiotic use, quality of life and a range of health economic measures.

Pharmaxis is developing Bronchitol as a treatment to improve mucus clearance in the lungs of patients with cystic fibrosis, bronchiectasis and chronic obstructive airway diseases.

Bronchitol is a patented, inhalable dry powder formulation of mannitol that can be administered by a convenient, hand-held pocket sized device.

Pharmaxis said cystic fibrosis is a fatal disease, affecting more than 75,000 people worldwide.

Pharmaxis was up eight cents or 3.64 percent to $2.28.

CYTOPIA

Cytopia says recruitment will begin for its phase Ib/II study of CYT997 for the brain cancer glioblastoma multiforme.

Cytopia said the glioblastoma multiforme clinical trial of CYT997, a vascular-disrupting anticancer agent, was the first phase II efficacy study in highly vascular, solid tumor indications for the company and the second in its suite of phase II studies designed to investigate the anti-cancer activity of CYT997.

Cytopia announced it had US Food and Drug Administration approval earlier this week (see Biotech Daily; September 1, 2008).

The company said the study would investigate the activity of CYT997 in combination with two other marketed anticancer agents, standard carboplatin and etoposide therapy in about 30 patients at clinical centers in Australia and overseas.

Frankston Hospital's director of oncology Dr Jason Lickliter is the study chairman for the program.

Cytopia climbed one cent or 4.76 percent to 22 cents.

PROGEN

Progen says that 25 percent of its workforce will be made redundant following the failure of its phase III clinical trial of PI-88 for liver cancer.

Progen said the 7.5 full time equivalent positions would be lost in administration, corporate manufacturing and regulatory affairs.

The company said these positions were "no longer required to support ongoing activities".

Progen said that Prof John Zalcberg had resigned as a non-executive director of the company after 13 years with the company.

Progen was up 1.5 cents or 2.27 percent to 67.5 cents.

VICTORIAN GOVERNMENT

Victoria's Innovation Minister Gavin Jennings has announced $25.7 million for 13 major medical research institutes to support daily operations in 2008-'09.

The funding includes $2.3 million to the Baker Heart IDI; $250,000 to the Bernard O'Brien Institute of Microsurgery; $430,000 to Bionic Ear Institute; $4 million to the Burnet Institute; $500,000 to the Centre for Eye Research Australia; $2.5 million to the Florey Neuroscience Institutes; $1.3 million to the Ludwig Institute for Cancer Research; $700,00 to the Mental Health Research Institute; $1.7 million to the Monash Institute of Medical Research; $2.2 million to the Murdoch Children's Research Institute; $100,000 to Prince Henry's Institute; $1.5 million to the St Vincent's Institute; and $7 million to the Walter and Eliza Hall Institute.

Mr Jennings said this funding was on top of $70 million in the August Innovation Statement "for the world's biggest life sciences computer and more programs to turn our biotechnology research into new treatments and drugs".

"The Brumby Government recognises leading-edge medical research requires funding for ongoing administration, equipment maintenance and building services and utilities costs," said Mr Jennings.

"So the Government established the Operational Infrastructure Support grants program to provide annual funding to support the day to day operations of our medical research institutes," Mr Jennings said.

VICTORIA, NEW SOUTH WALES GOVERNMENT

The Victorian and New South Wales governments will provide $455,450 to the Monash Institute of Medical Research and a NSW research team for stem cell research.
Victorian Innovation Minister Gavin Jennings and NSW Minister for Science and Medical Research Verity Firth said the research could lead to treatments for type 1 diabetes and infertility.
“This ground-breaking project will continue to keep Victoria and NSW at the forefront of global advancements in these new biological frontiers,” Mr Jennings said.
“The project will use somatic cell nuclear transfer technologies to create new disease specific stem cell lines using a patient’s own cells,” Mr Jennings said.
“Developing these new cell lines will aid research into creating better drugs for treating type 1 diabetes and new applications for infertility treatments,” he said.
Ms Firth said the project would also study the potential of the newly discovered cells generated from skin cells, known as induced pluripotent stem cells.
“This will include exploring new ways to generate these cells that avoids problems such as the generation of tumors that hamper their potential use for combating diseases,” Ms Firth said.
The project is the second to be funded out of a joint somatic cell nuclear transfer research program of $1 million contributed by the two Governments.

VIRALYTICS

Viralytics has appointed Paul Hopper as a non-executive director.
The company said the Los Angeles-based Mr Hopper had more than 20 years experience in the management and funding of biotechnology and healthcare public companies in Australia, Asia, US and Europe.
The company said Mr Hopper was a director of Psivida and Somnomed.
Viralytics said Mr Hopper was a consultant to the Santa Monica merchant bank Cappello Capital and New York life-sciences investment bank BIO:IB Inc and had served as executive chairman of Bone Medical.
Viralytics was unchanged at 5.6 cents.

HEALTHLINX

Healthlinx has appointed Dr Dominic Autelitano as chief scientific officer effective from September 1, 2008.
The company said Dr Autelitano was Healthlinx’s manager of peptide therapeutics.
Healhtlinx said Dr Autelitano received his Ph D from Monash University in 1986 and then was a Fulbright post-doctoral fellow at Columbia University Medical Center and Mt. Sinai School of Medicine in New York worked predominantly on peptide hormone characterization, gene expression and cellular signalling.
Dr Autelitano established a laboratory at Melbourne’s Baker Heart Research Institute before joining Cryptome Pharmaceuticals (now Healthlinx) as senior group leader of cell biology
Healthlinx was untraded at 5.3 cents.