Biotech Daily

Friday June 20, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: POLARTECHNICS UP 15%, STEM CELL DOWN 16%**

*** FDA GREEN LIGHTS PHARMAXIS' PHASE III BRONCHIECTASIS TRIAL**

*** METABOLIC SHUTS PROGRAMS, LOOKS FOR ACQUISITIONS**

*** ACRUX'S ROSS DOBINSON BUYS 3.4m ANZ OPES PRIME SHARES**

*** VIRALYTICS TALKS TOXICOLOGY WITH THE FDA**

*** GENERA SUPPLIES GRIBBLES WITH PAPTYPE HPV GENOTYPE TEST**

*** PORTLAND REQUESTS CAPITAL RAISING TRADING HALT**

*** INSYMBIOSIS TO CODEVELOP HEALTHLINX'S CR014 LUNG DRUG**

*** PEPLIN APPOINTS DR GARY PATOU CHIEF MEDICAL OFFICER**

*** IM MEDICAL CEO TOMMAS BONVINO 'PURSUES NEW OPPORTUNITIES'**

MARKET REPORT

The Australian stock market fell a further 1.3 percent on Friday June 20, 2008 with the All Ordinaries down 72.5 points to 5,411.8 points. Eleven of the Biotech Daily Top 40 stocks were up, 16 fell, seven were unchanged and six were untraded.

Polartechnics was best, up two cents or 15.38 percent to 15 cents on small volumes, followed by Cytopia up three cents or 15.0 percent to 23 cents and Sunshine Heart up half a cent or 10 percent to 5.5 cents.

Impedimed climbed 7.14 percent; Genetic Technologies was up 6.06 percent; Acrux rose 4.12 percent; Phylogica was up 3.26 percent; with Peplin and Universal Biosensors up more than one percent.

Stem Cell Sciences led the falls, down 6.5 cents or 15.66 percent to 35 cents on small volumes, followed by Agenix down 13.46 percent to 4.5 cents.

Prana lost 6.82 percent; Clinuvel and Ventracor were down more than five percent; Alchemia, Avexa and Pharmaxis fell more than four percent; Biota, Cellestis and Heartware were down more than three percent; with Antisense, Arana, Mesoblast, and Starpharma down more than one percent.

PHARMAXIS

The US Food and Drug Administration approved Pharmaxis' phase III registration trial of Bronchitol for bronchiectasis through a special protocol assessment process.
The process allows FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a new drug application and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. Pharmaxis previously agreed on the trial design with the European Medicines Agency (EMEA).
The trial will form the basis of a marketing application in both the US and Europe.
The phase III trial will be a randomized, placebo controlled, double-blind investigation of Bronchitol twice daily in approximately 350 adults with bronchiectasis.
Participants will be treated for 52 weeks and the primary endpoints are reduction in frequency of exacerbations and improvement in quality of life.
Pharmaxis has previously said that European and US definitions of the primary endpoints had prevented earlier agreement (see Biotech Daily May 2, 2008).
Secondary endpoints include time to first exacerbation and duration of exacerbation.
Additional secondary endpoints are antibiotic use, sputum volume, exercise tolerance and lung function measurements.
The trial will be conducted in centers across Europe and the US beginning in the next months, with data expected by mid-2010.
This trial is the second phase III study to be undertaken for Bronchitol in bronchiectasis and follows the completion of a successful shorter trial reported last year.
Pharmaxis chief executive officer, Dr Alan Robertson, said the company was pleased to have concluded its discussions with the FDA and the EMEA.
"We believe this phase III trial design will allow us to thoroughly demonstrate the clinical benefits of Bronchitol in a patient population for which mucus build-up and clearance is a daily problem," Dr Robertson said.
"Our bronchiectasis program follows closely behind our work in cystic fibrosis where a phase III clinical trial is expected to soon close recruitment," he said.
The FDA has granted Bronchitol fast track status and it is designated as an orphan drug.
Pharmaxis fell seven cents or 4.14 percent to $1.62.

METABOLIC

Metabolic is closing down or selling its pipeline and is actively seeking merger and acquisition opportunities with its $16 million in cash.
The company said that rebuilding the pipeline was "too lengthy a process".
Metabolic said it expected to begin the 2008-'09 financial year with $16 million in cash and interest bearing deposits, after allowing for downsizing costs.
The oral peptide delivery platform has been placed on hold and the in-house laboratory has been closed.
Metabolic said the neural regeneration peptides project with Neuren was awaiting results of further animal studies.
Results from a 2007 study with a rodent model of motor neuron disease using NNZ04945 showed the drug extended the life expectancy of mice with this disease.
Metabolic said it was awaiting results of further animal studies to confirm the potential value of the neural regeneration peptides.
The company said its osteoporosis drug AOD9604 may treat the disease as well as prevent it and it would attempt to licence the drug.
Metabolic fell 0.2 cents or 4.65 percent to 4.1 cents with 5.3 million shares traded.

ACRUX

Acrux chairman Ross Dobinson has bought back into the company after losing his 9.133 percent holding in the Opes Prime Stockbroking collapse.

In a notice to the ASX, Acrux said that in late March 2008 Mr Dobinson "had his shareholding of approximately nine percent of Acrux seized by [the ANZ Bank] following the collapse of Opes Prime".

As previously reported, Acrux first informed the market that the holding of 14,549,015 shares or 9.133 percent of the company was held by chairman Ross Dobinson and associate entities on April 8, 2008.

Mr Dobinson told Biotech Daily the holding was his on April 7.

In the Federal Court Judge Raymond Finkelstein has ruled on May 2, 2008 that shares loaned to Opes Prime under an Australian Master Securities Lending Arrangement were the investor's liability and they were subsequently legitimately acquired by the ANZ when Opes Prime collapsed.

Acrux said Mr Dobinson unsuccessfully tried to negotiate the repurchase of that stake from ANZ prior to its sale by Goldman Sachs JB Were.

Today Acrux said Mr Dobinson subsequently repurchased 3,355,866 shares from Walker Group Holdings, the buyer of most of his former shareholding.

In a separate director's interest statement today, Mr Dobinson said he bought the shares off market for 90 cents a share.

It is believed this holding is not subject to any lending arrangement, but Mr Dobinson was not available for comment.

Acrux said Mr Dobinson had reserved his rights in relation to claims against the ANZ for the loss of his original shareholding.

Mr Dobinson said: "I have absolute confidence in Acrux's future with the commercial release of a range of products incorporating the Acrux transdermal drug delivery technology."

Acrux climbed four cents or 4.12 percent to $1.01.

VIRALYTICS

Viralytics has begun discussions with the US Food and Drug Administration on toxicology studies of its lead oncolytic virus product, Cavatak.

Viralytics has requested the FDA review and comment upon its planned toxicology program.

Discussions will be focused on the proposed formal toxicology program leading up to the initiation of an FDA-approved phase II clinical evaluation of Cavatak.

Viralytics said it had engaged the services of an Australian clinical toxicologist and a US-based pharmaceutical toxicologist to assist in the development of the overall toxicology strategy, based on substantial pre-clinical research on the mode of action of Cavatak and exciting toxicological data generated in a European research collaboration, involving the use of a novel animal model.

Viralytics' director of clinical research and regulatory affairs Dr Phillip Altman said the FDA had already granted Viralytics orphan drug status for Cavatak in patients with stage II(T4)/III/IV melanoma, potentially accelerating the product registration.

Viralytics said its decision to enter into detailed discussions with the FDA followed the recent granting of a cornerstone US patent and notice of allowance of a similar patent in Europe.

Viralytics was up 0.3 cents or 4.62 percent to 6.8 cents.

GENERA BIOSYSTEMS

Genera Biosystems will supply its Paptype human papilloma virus detection test to Gribbles Pathology, part of Healthscope Limited.

Genera said the agreement would run until 2010, with a five year extension by mutual agreement and sales commencing in July 2008.

Genera chairman Fernando Careri said it was “further commercial validation for Genera’s technology”.

“We look forward to continuing to work with Gribbles on this and other projects in our product pipeline in the future,” Mr Careri said.

Genera said high-risk human papilloma virus (HPV) infection caused cervical cancer, a disease which is responsible for the death of more than 200,000 women around the world every year.

The company said some genetic variations (genotypes) of HPV were more dangerous than others and there was substantial clinical value in being able to offer a test that facilitated detection and genotyping.

Paptype was originally developed in collaboration with Gribbles, who were in the market for a simple, reliable, and cost-effective HPV genotyping product.

Gribbles’ head of molecular pathology Dr Keith Byron said of the Genera test “not only is it highly cost-effective, the HPV genotyping information that it generates helps Gribbles provide doctors with more precise and actionable clinical information”.

Genera chief executive officer Dr Allen Bollands said Paptype could be run using a smaller sample volume than current tests, reducing the chance of a non-result.

Genera said corporate interest was reaffirmed this week with Hologic’s proposed $US580 million acquisition of Third Wave Technologies, which has developed a high risk screening HPV test and also a type 16 and18 genotyping test.

Genera said these tests have yet to be approved by the US Food and Drug Administration but the company has filed its application with the objective of gaining US approval in 2009.

Dr Bollands said Paptype compared favorably with the Third Wave product suite.

He said the rival company’s strategy was “to initially screen patients for high-risk HPV using a non-genotyping test, then genotype those specimens found to be high-risk HPV positive using a second test”.

“Not only does Paptype detect and genotype in a single test, it genotypes all 14 high-risk types of HPV, rather than just types 16 and 18,” Dr Bollands said.

Genera said it would continue to seek additional partnerships and commercial supply agreements for Paptype.

Gribbles is Australia’s third largest pathology company and has validated Paptype for clinical use in its laboratories using guidelines produced by the Commonwealth government’s National Pathology Accreditation Advisory Council.

Genera will be filing Paptype for broader approval with the Australian Therapeutic Goods Administration and other regulatory jurisdictions in 2009.

Genera fell four cents or 8.89 percent to 41 cents.

PORTLAND

Portland has requested a trading halt pending an announcement regarding “a material capital raising”.

Trading will resume on June 24, 2008 or on an earlier announcement.

Portland last traded at 2.4 cents.

HEALTHLINX

Canada's Insymbiosis Discovery will co-develop Healthlinx's peptide therapeutic CR014 and related compounds for acute respiratory distress syndrome and acute lung injury.
Healthlinx said it had terminated the previously announced intention to spin off CR014 to Proaegis (see Biotech Daily October 17, 2007).
Healthlinx said the companies would proceed under a joint venture agreement subject to the completion of due diligence.
Healthlinx said acute respiratory distress syndrome (ARDS) was a complex syndrome affecting the vital functions of the lungs for which there were no effective therapeutic treatments available and 30-40 percent of patients who develop this syndrome will die.
CR014 has demonstrated efficacy in reducing the adverse effects of lung injury in an animal model of the syndrome.
The proposed joint venture will conduct a full pre-clinical evaluation of CR014 with a view to progressing to clinical trials.
Healthlinx chairman Greg Rice said the joint venture with Insymbiosis was "a good opportunity" to continue to extract value from its therapeutic assets while maintaining the company's primary focus and resource commitment to delivering new diagnostics such as the ovarian cancer diagnostic, Ovplex.
"A successful outcome of the joint venture would position CR014 as a lead candidate for clinical evaluation in the treatment of not only ARDS but other related lung syndromes," Mr Rice said.
Healthlinx said CR014 was licensed in from the University of Virginia in 2006 and has been further developed by Healthlinx.
The compound is a novel natural human peptide that inhibits aberrant vascular permeability and associated inflammation after acute lung injury.
Healthlinx fell 0.9 cents or 10.23 percent to 7.9 cents.

PEPLIN

Peplin has appointed Dr Gary Patou as its consultant chief medical officer on an interim basis.
The company said Dr Patou previously served in this role from June 2006 to April 2007.
Dr Patou is a managing director at MPM Capital and has broad experience in drug development, most recently as chief medical officer of Oscient Pharmaceuticals, following its merger with Genesoft Pharmaceuticals in 2004.
Peplin said Dr Patou was previously president of Genesoft where he was "instrumental in applying for and obtaining FDA approval of the company's lead product, Factive tablets".
Prior to Genesoft, Dr Patou worked at Smithkline Beecham, now a unit of Glaxosmithkline, as director of project and portfolio management.
The company said Dr Patou would be interim consultant chief medical officer until a permanent appointment was made.
Peplin chief executive officer Michael Aldridge said the company expected to start two late stage phase IIb and phase III clinical trials "imminently".
"Gary's oversight of those trials and his considerable experience in drug development will be valuable as we deliver results and approach our important end of phase II meeting with [the] FDA," Mr Aldridge said.
Peplin was up half a cent or 1.27 percent to 40 cents.

IM MEDICAL

IM Medical says chief executive officer Tommas Bonvino is leaving the company "after completing the important task of implementing new strategic directions".

IM Medical chairman Dipak Sanghvi said Mr Bonvino was leaving with the board's best wishes and gratitude for his achievements in the past two years.

"Tommas has set the foundations for the company's future growth and has put in place an excellent management team capable of rolling out our products," Mr Sanghvi said.

"He was appointed by the board to refocus the marketing strategy for our products. In the past, our strategy was focused almost solely on medical practices. Tommas has opened up the consumer and workplace markets which are now coming to fruition.

"His most recent achievement was perhaps his finest, the negotiation of an alliance with Sigma to sell Intelliheart in more than 700 pharmacies around Australia," Mr Sanghvi said.

Mr Bonvino said he was leaving the company to pursue other opportunities.

Chief financial officer and company secretary Roman Najdecki will act as CEO pending a search for a permanent replacement.

Mr Sanghvi will also play a more hands-on role.

IM Medical closed down 0.1 cents or 5.56 percent to 1.7 cents with 16.3 million shares traded.