Biotech Daily

Thursday April 26, 2007

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECHS SPLIT: BIOTA UP 9%, POLARTECHNICS DOWN 9%**

*** ALCHEMIA HAT-TRICK:**
- *** 'STARTLING' PHASE II CANCER RESULTS**
- *** DR REDDY'S PARTNERS SYNTHETIC HEPARIN**
- *** DR PETER SMITH REPLACES CEO DR TRACIE RAMSDALE**

*** WESTERN AUSTRALIA FUNDS $10m TRIALS CENTRE**
*** VIRALYTICS IN CANADIAN BRAIN CANCER COLLABORATION**

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*** NUCARE TO DISTRIBUTE ROCKEBY'S VAGINAL THRUSH TEST**
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THE MARKET

The Australian stock market climbed 0.4 percent on Thursday April 26, 2007, with the All Ordinaries up 24.5 points to 6,197.8 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell and nine traded unchanged. Thirteen of the Top 20 stocks were up and four fell, while two of the Second 20 rose and 12 fell.

Biota was best up 14 cents or 8.64 percent to $1.76 with 2.5 million shares traded, followed by Alchemia up eight cents or 7.48 percent at $1.15 with 1.8 million shares traded.

Phylogica climbed 2.5 cents or 7.46 percent to 36 cents; Bionomics was up 6.56 percent to 32.5 cents; Mesoblast climbed 4.48 percent to $2.10; Cochlear, CSL, Pharmaxis and Resmed climbed more than two percent; with Cytopia, Evogenix, Neuren, Prana and Ventracor up more than one percent.

Polartechnics fell the furthest down five cents or 9.09 percent to 50 cents followed by Clinuvel down 9.5 cents or 8.23 percent to $1.06. Progen and Genetic Technologies fell more than seven percent; Clinical Cell and Proteome slid more than six percent; Portland lost 5.88 percent; Psivida shed 4.65 percent; Living Cell and Optiscan fell more than three percent; Avexa, Cellestis and Prima fell more than two percent; with Peplin, Peptech and Tissue Therapies down more than one percent.

ALCHEMIA: 'Startling' Hycamp Phase II Results

Alchemia says its Hycamp compound has shown significantly better efficacy in a randomized phase II clinical trial of patients with metastatic colorectal cancer than irinotecan, "a cornerstone drug" for the treatment of colorectal cancer.

In notices to the ASX Alchemia simultaneously reported that Dr Peter Smith would replace Dr Tracie Ramsdale as chief executive officer and that Dr Reddy's Laboratories will be its marketing partner for synthetic heparin for North America (see below).

The company said the Hycamp trial primary safety endpoint was not met due to lower than expected incidence of diarrhoea in the control arm.

In a telephone conference, principal investigator Prof Peter Gibbs said that the primary endpoint had been rendered meaningless by the significant efficacy data. He said that neutropenia was the same in both arms of the trial despite a three-fold dosing of Hycamp.

The secondary safety endpoints showed "no major differences in overall adverse events between the two treatment arms" but in the secondary efficacy endpoints Alchemia said that 38 of 41 (93%) Hycamp patients compared to 28 of 35 (80%) irinotecan patients completed two treatment cycles (p=0.099); 14 of 41 (34%) Hycamp patients compared to 5 of 35 (14%) irinotecan patients completed the full eight cycles (p=0.064); patients on Hycamp received a median of six cycles of therapy, compared to two for irinotecan alone (p=0.005); median progression-free survival for Hycamp patients was 5.2 months, compared to 2.4 months for the irinotecan arm (p=0.014).

Eighty patients with metastatic colorectal cancer who previously failed treatment with the anti-cancer drug 5-fluoro uracil were eligible to receive up to eight cycles of chemotherapy in the form of irinotecan or Hycamp intravenously.

The primary endpoint of the trial was safety (incidence of grade 3/4 diarrhoea) with secondary safety and efficacy endpoints of disease control, progression free survival and overall survival.

Alchemia said the two arms of the study were "very well balanced for known prognostic factors". Preliminary data regarding toxicity indicated no major differences between the two arms, with Hycamp associated with less cumulative toxicity because the Hycamp arm received significantly more doses. The overall incidence of grade 3/4 diarrhoea was lower in this study (14%) than anticipated, presumably reflecting improved medical management of this side effect and thereby impeding any meaningful analysis of this endpoint.

Patients on Hycamp received a median of six cycles of therapy, compared to two for irinotecan alone (p=0.005).

Median progression free survival for Hycamp patients was 5.2 months, compared to 2.4 months for the irinotecan arm (p=0.014). Preliminary data indicates the proportion of patients exhibiting disease control (complete responses, partial responses or stable disease) in the Hycamp arm was at least 40 percent greater than in the irinotecan arm.

Full results are expected by the end of May.

Principal investigator Prof Peter Gibbs said the findings "have far exceeded our expectations in that we did not expect to achieve a statistically significant improvement in efficacy from such a small number of patients".

Dr Ramsdale says Alchemia "will be moving as quickly as possible to discuss our plans for future studies with the FDA".

"We are hopeful that these results will enable us to move forward to a pivotal phase III study earlier than originally anticipated," Dr Ramsdale said.

These results are important not only for the development and approval path for Hycamp itself but they provide validation of the technology platform.

The Hyact platform is a flexible formulation technology and can be used "with virtually any intravenously administered anti-cancer treatment" Dr Ramsadale said.

“We have successfully completed phase I clinical studies on Hyact formulations of two other chemotherapy drugs, doxorubicin and 5-flurouracil. Encouraging preclinical data has also been obtained on a number of other cytotoxics. More recently, we have demonstrated in preclinical studies that Hyact can also be used to significantly enhance the efficacy of newer targeted antibody therapies such as Avastin and Erbitux.
Alchemia will prepare for discussions with the US Food and Drug Administration for a pivotal phase III trial.

Synthetic Heparin Partner

Alchemia has granted Dr Reddy’s the exclusive rights to market its synthetic heparin in North America, with first right of refusal to market the product in the European Union when the Glaxosmithkline drug Arixtra’s market exclusivity expires in 2012.
Dr Reddy’s will be responsible for the development of the active pharmaceutical ingredient, the finished product and all regulatory filings including the submission of an abbreviated new drug application (ANDA).
Alchemia and Dr Reddy’s will share profits equally from finished product sales, with Alchemia’s share increasing to 60 percent if sales of Arixtra exceed a certain level at the time of commercialization of its product.
Separately Alchemia has transferred the manufacturing rights from Dow Pharmaceuticals under licence to Dr Reddy’s Laboratories in Hyderabad, India. Dow, which produced batches of synthetic heparin at pilot scale, will receive a royalty on Dr Reddy’s sales of bulk synthetic heparin.
Alchemia said Dr Reddy’s was a leader in the US generic drug market where it has 31 approved ANDAs (generic drug approvals) and has 58 pending final approval.
The company has a marketing presence in India, Germany, Russia and China.

CEO Succession

Alchemia’s commercialization director Dr Peter Smith has replaced Dr Tracie Ramsdale as chief executive officer, effective immediately.
Dr Ramsdale has been Alchemia’s CEO since its inception in 1998. She will remain a non-executive director, chair the scientific advisory board and be a consultant to the company.
Dr Smith has founded and led biotech companies in the UK and Australia and has 10 years experience as an industry analyst with investment banks UBS and HSBC.
Dr Smith was chief executive officer and managing director of Amrad Corporation (2003-05) where he implemented a strategy focusing Amrad (later Zenyth) on antibody-based therapies. Zenyth was acquired by CSL in 2006 and as part of the reorganization Amrad created the spin-out anti-infective company Avexa.
Dr Ramsdale said Dr Smith was “one of the most experienced and widely respected executives in the Australian biotech industry”.
“I have worked closely with Peter for the past year and I am convinced he is the right person to lead Alchemia through its next phase of critical growth,” Dr Ramsdale said.
“His international network of relationships has been instrumental in securing the new manufacturing and marketing partnerships for synthetic heparin announced today, adding significant value to Alchemia going forward,” said Dr Ramsdale (see below).
Dr Smith said the prospect of near-term revenues from heparin and the potential to expand the clinical development portfolio in oncology “following the startling phase II Hycamp results” will drive medium-term value for shareholders.
Mr Bridges said the appointment of Dr Smith completed a succession plan following Dr Ramsdale’s intention to retire.
Alchemia closed up eight cents or 7.48 percent at $1.15 with 1.8 million shares traded.

WESTERN AUSTRALIA GOVERNMENT

The Western Australia state government has allocated $9.95million to the Western Australian Institute for Medical Research for a clinical trials facility at the Sir Charles Gairdner Hospital site in Nedlands.

A media release from Premier Alan Carpenter and Industry and Enterprise Minister Francis Logan said the facility had "the potential to test new treatments for cancer, diabetes and heart disease".

The government release said the facility would allow local and international biotechnology and pharmaceutical companies to take part in world-class early phase clinical research.

It will be the first of its kind in Western Australia and is expected to open in 2008.

Mr Carpenter who is also his state's Science Minister said the facility would raise the profile of his states biotechnology and health and medical research industry.

"At the moment, there is no dedicated facility in WA for pharmaceutical companies or researchers to conduct early phase clinical trials," he said. "This 24-bed facility will create a coordinated and centralized centre dedicated to high-quality clinical research."

"The facility will enable patients to have early access to ground-breaking treatments which have the potential to improve their quality of life," Mr Carpenter said.

"It also furthers the Government's commitment to diversifying the State's economy beyond the current resources boom."

Mr Logan said the clinical trials facility would provide critical infrastructure for Western Australia's local biotechnology sector and attract companies to invest in the state.

"This funding will provide local biotechnology companies with a dedicated world-class facility in which to carry out clinical trials of new drugs or equipment developed in WA," Mr Logan said.

"It will not only benefit WA's local industry, it will also create economic opportunities for the State's medical research sector from global pharmaceutical companies looking for a world-class clinical trials facility," he said.

VIRALYTICS

Viralytics will collaborate on brain cancer with Toronto neurosurgeon, Prof Abhijit Guha and has received a $369,000 National Health and Medical Research Council grant for researcher, Dr Gough Au to undertake research in this project.

The research collaboration will investigate the oncolytic action of Cavatak on human brain cancers most commonly referred to as glioblastomas.

It will include assessing the capacity of three of Viralytics' oncolytic viruses including Cavatak to target and destroy cancerous cells extracted from surgically removed human glioblastomas, as well as testing in sophisticated animal models of Glioblastoma.

Prof Guha said the use of oncolytic viruses, as potential anti-cancer agents against glioblastomas, was "an attractive approach".

"I am hopeful, that the exciting pre-clinical oncolytic activity of Cavatak currently observed in a number of different cancer cell lines may extend into anti-cancer activity in glioblastomas," Prof Guha said.

Dr Guha is professor of neurosurgery at the University of Toronto and practices at the Toronto Western Hospital.

Malignant gliomas are the most common tumors of the central nervous system and often respond poorly to surgery, radiotherapy and chemotherapy. The disease is often fatal, usually within 1-2 years of the onset of symptoms, despite conventional therapy.

Viralytics was unchanged at 8.1 cents.

BENITEC

Benitec says the European Patent Office has refused to issue a European patent application (published as EP1071762).

The appeal hearing was held in Munich yesterday and heard arguments from both Benitec and the Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Benitec said the application was rejected for formal reasons and not for novelty and obviousness. Benitec and CSIRO will pursue these patent claims through the divisional applications already on file.

Benitec chief executive officer Sue MacLeman said that while her company was "disappointed" with the outcome, "we will be reviewing our options with CSIRO and our patent attorneys".

"There has never been any doubt in our minds about the patentability of our invention and we have other options to pursue claims for this invention," Ms MacLeman said.

Benitec also said it had filed a response to the US Patent and Trademark Office's January 24, 2007 action for re-examination of a patent.

Benitec says its April 24 submission "fully responds to all of the issues raised by the Patent Office and persuasively explains why the prior art did not anticipate or render obvious the claims under re-examination".

Benitec fell four cents or 19.05 percent to 17 cents with 3.8 million shares traded.

BIOTA

Biota has received notification from Glaxosmithkline that indicative royalties for Relenza were $16 million during the three months ended March 31, 2007, based on sales of STG92 million ($A220.8 million).

Biota said that along with the $5.4 million royalty for in the three months to September 30 2006 and the $7.3 million for the three months to December 31 2006, the company had received a total of $28.7 million for the nine month period.

Chief executive officer Peter Cook said that the sales of STG92 million for the quarter made Relenza "the fourteenth largest product, ranked by turnover" within Glaxosmithkline's global product range.

Biota was up 14 cents or 8.64 percent to $1.76 with 2.5 million shares traded.

CLINUVEL

Clinuvel has raised $26 million through a private placement and may raise up to $15 million through a share purchase plan.

Clinuvel said it had placed 24,339,054 shares at $1.07 to Australian and European institutions.

Shareholders in Australia and New Zealand will be entitled to participate in the share plan and can apply for up to $5,000 worth of shares. If all shareholders took up the maximum allocation, Clinuvel could raise up to $15 million.

The record date is May 8, 2007 and the plan will close on May 31, 2007, but the company said it would ill reserve the right to extend the closing date.

The proceeds will be used to fund clinical trials of CUV1647 in the fifth indication in Photodynamic Therapy and to continue ongoing development of its technology.

Clinuvel fell 9.5 cents or 8.23 percent to $1.06.

ROCKEBY

Rockeby Biomed has appointed the UK-based Nucare Group to market and distribute its Candia5 rapid test to detect vulvovaginal candidiasis or vaginal thrush.
The deal is for five years, with exclusivity for the first two years.
Rockeby said minimum annual purchases by Nucare have been set under the agreement which also covers other diagnostic tests produced or sold by Rockeby in the future.
The test has received European over the counter designation.
Rockeby said Nucare was a public company with 700 shareholders, many of whom are also independent pharmacists and customers of its Nucare Services business.
Rockeby says Candia5 is "the first and only qualitative immunochromatographic point-of-care rapid test device" designed for the detection of antibodies of the IgG class in human whole blood or serum that react with purified cellular candida antigens. It is used for the accurate detection of vulvovaginal candidiasis within six minutes.
Rockeby fell 0.1 cents or 3.57 percent to 2.7 cents.

SIRTEX

Hunter Hall Golbal Value and associated companies have become substantial shareholders in Sirtex with 3,027,386 shares (5.43%).
The investment companies increase their holding in small parcels from March 30 2004 and became substantial on February 16 2007.
Sirtex closed up two cents or 0.55 percent to $3.66.

XCEED, BORON

Xceed Biotechnology's subsidiary, Boron Molecular has appointed Dr Scott Courtney as managing director
Formerly Boron Molecular's production and operations manager, Dr Courtney replaces Dr John Tsanaktsidis who has completed a two year secondment and returns to the Commonwealth Science and Industrial Research Organisation.
Prior to joining Boron Molecular, Dr Courtney was employed at the Institute of Drug Technology.
Boron Molecular provides novel organo-boron building-block molecules and synthesis services to the pharmaceutical, biotech and fine chemical industries. The company's technology platform was originally developed by CSIRO.
Xceed fell 1.5 cents or 6.98 percent to 20 cents.