Biotech Daily

Thursday October 23, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: GENETIC TECHNO UP 20%, BIOTA DOWN 20.5%**

*** BENITEC 'VERY ENCOURAGED' BY RNAi HIV LYMPHOMA TRIAL DATA**

*** GENETIC TECHNOLOGIES' CANCER TESTS CHALLENGED**

*** VICTORIAN GOVERNMENT OFFERS $41m FOR PARTNERSHIPS**

*** US FDA APPROVES ALCHEMIA'S PHASE III BOWEL CANCER TRIAL**

*** BIOTA FALLS 20.5% ON GSK RELENZA ROYALTY**

*** LIVING CELL TO BUILD PATHOGEN- FREE PIG BREEDING FACILITY**

*** PRIMA FDA MEETING LEADS TO OVARIAN CANCER APPLICATION**

*** VIRALYTICS RESTRUCTURES BOARD, MANAGEMENT**

*** RESONANCE PROMOTES LIZA DUNNE TO M-D**

*** IM MEDICAL VOTES ON 18.7m STAFF SHARES, PLACEMENT, DIRECTORS**

MARKET REPORT

The Australian stock market fell 4.4 percent on Thursday October 23, 2008 with the All Ordinaries down 180.8 points to 3,939.3 points.

Nine of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and 10 were untraded.

Genetic Technologies was best, up 0.9 cents or 19.57 percent to 5.5 cents on small volumes, followed by Benitec up 0.8 cents or 17.02 percent to 5.5 cents with 1.1 million shares traded and Phylogica up 12.9 percent to seven cents. Cellestis climbed 6.13 percent; Chemgenex and Optiscan were up more than three percent; Living Cell rose 2.63 percent; with Novogen and Peplin up more than one percent.

Biota led the falls, down 8.5 cents or 20.48 percent to 33 cents, followed by Polartechnics down 13.68 percent to 8.2 cents. Alchemia lost 6.82 percent; Bionomics and Pharmaxis fell more than five percent; Cytopia, Progen and Ventracor fell more than four percent; Cochlear was down 3.81 percent; Acrux, CSL and Resmed shed more than two percent; with Prana and Viralytics down more than one percent.

BENITEC

Benitec says all three HIV patients treated in its first human clinical trial with California's City of Hope research centre have "responded positively".

Benitec chief executive officer Sue MacLeman told Biotech Daily the early results showed that following a complex bone marrow modification and transplantation "three patients have been treated and all have responded positively and a fourth patient is awaiting treatment".

Ms MacLeman said the results had been presented by the Beckman Research Institute's chair of Virology Dr John Zaia at Cambridge Healthtech Institute's 'RNAi for Therapeutics' conference in Boston, October 22-23, 2008.

Benitec said Dr Zaia was a key collaborator for the pilot human HIV study being undertaken at the City of Hope in Duarte, California.

In his oral presentation entitled 'Delivery of shRNA and other anti-HIV RNAs by autologous transplantation of lentivirus-transduced cells - a feasibility study' Dr Zaia said the final outcomes of the study were still pending "however to date we have seen safe engraftment in three patients at 10 days".

"We have also seen gene markers in the blood months later which is very encouraging," Dr Zaia said.

The Benitec, City of Hope collaboration is Benitec's first human trial and uses a triple therapy delivered using a lentiviral vector for the treatment of HIV.

The study, entitled 'A pilot study of the safety and feasibility of stem cell therapy for AIDS lymphoma using stem cells treated with a lentiviral vector-encoding multiple anti-HIV RNAs' is designed to determine the safety and feasibility of RNA-based anti-HIV therapy with lentivirus-transduced hematopoietic progenitor cells in patients undergoing autologous haematopoietic stem cell transplantation for intermediate and high grade AIDS lymphoma.

The rHIV7-shl-TAR-CCR5RZ vector suppresses HIV by expressing three therapeutic nucleic acids that are directed against key steps in HIV replication.

The rHIV7-shI-TAR-CCR5RZ vector is used to transduce autologous CD34-selected haematopoietic progenitor cells and was manufactured by the Center for Biomedicine and Genetics at City of Hope.

The lentivirus vector encodes three forms of anti-HIV RNA: RNAi in the form of a short hairpin RNA (shRNA) targeted to an exon in HIV-1 tat/rev (shI); a decoy for the HIV TAT-reactive element (TAR); and a ribozyme that targets the host cell CCR5 chemokine receptor (CCR5RZ).

Following standard mobilization of haematopoietic progenitor cells (HPC) and collection by apheresis (HPC-A), a portion of the cells were cryo-preserved and left unmanipulated for later use as treatment.

The remaining cells were enriched for CD34+ cells using a Miltenyi Clinimacsm system, cryo-preserved and later genetically modified by infection with rHIV7-shI-TAR-CCR5RZ.

The subjects underwent conditioning therapy and at the time of autologous haematopoietic stem cell transplantation, the rHIV7-shI-TAR-CCR5RZ transduced cells were infused, followed 24 hours later by the infusion of untransduced autologous HPC-A.

Ms MacLeman said Benitec was "very encouraged" by the initial findings.

"This is an extremely important trial as it is the first human clinical trial with expressed RNA interference trigger (shRNA) and the first triple gene therapy combination trial for HIV/AIDS," Ms MacLeman said.

"It is the also the first human trial for AIDS using lentiviral vectors transduced with hematopoietic stem cells," she said.

Benitec climbed 0.8 cents or 17.02 percent to 5.5 cents with 1.1 million shares traded.

GENETIC TECHNOLOGIES

Recent media reports have highlighted some concerns over Genetic Technologies proposal to protect its intellectual property rights for cancer testing.

The Cancer Council of Australia has been quoted in some media expressing concern over the issuing of patents over human biological material.

Genetic Technologies has said it would “enforce the rights … to use Myriad’s patents to perform diagnostic testing of the BRCA1 and BRCA2 genes in Australia and New Zealand”(see Biotech Daily; July 11, 2008).

Genetic Technologies chief executive officer Michael Ohanessian told Biotech Daily in July that the genes were markers for a predisposition to inherited breast and ovarian cancer.

Mr Ohanessian said the company had not enforced its rights to the exclusive licence acquired in October 2002 from Myriad Genetics to perform diagnostic testing in Australia and New Zealand.

The Cancer Council Australia familial cancer spokesperson Dr Graeme Suthers told Biotech Daily there were “fundamental problems with patenting genetic sequences and that establishing monopolies over medical technology could set a problematic precedent”.

“DNA is human biological material and its identification should not constitute a patentable inventive step, a point the Cancer Council made to a recent review of patentable subject matter conducted by the Advisory Council on Intellectual Property,” Dr Suthers said.

“Moreover, as shown in Canada, the establishment of a monopoly over genetic testing has the potential to see the price of procedures increase and access to testing reduced,” Dr Suthers said.

“Monopolies in medical technology can pose other fundamental problems,” he said.

“With only a single service provider, comparisons between laboratories that guarantee quality and continuous improvement may be impossible,” Dr Suthers said.

“Testing of BRCA genes is complex, both in technical terms and in the interpretation of results, he said.

“This testing is an integral component of the training and accreditation of genetic scientists in Australia,” Dr Suthers said

“The loss of BRCA testing from public sector labs - the principal providers of such training - could lead to problems in recruiting, training and retaining genetic scientists in the public sector,” Dr Suthers said.

Mr Ohanessian said in July that public sector laboratories had been performing the tests and they were aware the Genetic Technologies had the rights but had chosen not to enforce those rights.

Mr Ohanessian said his company had been building its capacity to do this testing.

He said Genetic Technologies was aware it was an emotive subject and the company would ensure there was a smooth transition with no interruption to services.

Mr Ohanessian did not say whether Genetic Technologies was seeking a royalty payment from the existing laboratories or was seeking to prevent them undertaking the test.

Genetic Technologies said it had a turnaround time “of just four weeks, in stark contrast to certain other laboratories that … had an average turnaround time of up to 11 months”.

One media report said the Australia Consumer and Competition Commission was conducting an inquiry into the matter.

A spokeswoman for the Australia Consumer and Competition Commission said the organization neither confirmed nor denied the existence of its inquiries, but made announcements relating to prosecutions when that occurred.

Genetic Technologies climbed 0.9 cents or 19.75 percent to 5.5 cents.

VICTORIAN GOVERNMENT

The Victorian Government has launched a $41 million Science Agenda Investment Fund "to help turn Victorian science and technology ideas into new products and services".
In a media release Innovation Minister Gavin Jennings said Victoria's science and technology community and industry were being encouraged to apply for funds to assist them to collaborate and pursue market opportunities.
"The Brumby Government is taking action to boost our already world-class science and technology base to generate new economic and social benefits for all Victorians," Mr Jennings said.
"This funding provides a great incentive for business and research institutions to form consortia and apply for funds to accelerate the conversion of their ideas into tangible solutions," Mr Jennings said.
According to the Fund's website www.business.vic.gov.au/vsa up to $41 million is available in 2009-'10 for collaborative projects between business and research organizations that strengthen Victoria's science and technology capabilities and deliver tangible outcomes in the areas of productivity, sustainability and/or health.
Grants of between $300,000 and $3 million will be provided for eligible projects.
Projects are expected to commence no later than January 2010.
Applications are now open, with expressions of interest closing on February 13, 2009.

ALCHEMIA

Alchemia has received approval from the US Food and Drug Administration for its investigational new drug application for HA-Irinotecan Solution for Infusion.
Alchemia said the FDA determined that it was safe to proceed with phase III human clinical trials for the treatment of metastatic colorectal or bowel cancer.
Alchemia chief executive officer Dr Peter Smith said the decision was "a critical step in the progression of HA-Irinotecan towards registration".
"Colorectal cancer is a major disease, and success in this next trial will open up a large potential market," Dr Smith said.
The company said the primary objective of the registration study would be to substantiate the successful phase II clinical data and demonstrate the superior efficacy of its drug.
Alchemia said the phase II trial demonstrated a statistically significant benefit of Alchemia's product compared to irinotecan alone, with a 116 percent increase in progression-free survival (p=0.014).
The earlier phase I and phase II clinical studies of HA-irinotecan were conducted under the Australian Clinical Trials Notification scheme.
More than 148,000 new cases of colorectal cancer and more than 49,000 deaths from the disease are estimated to occur in the US in 2008.
Alchemia fell 1.5 cents or 6.82 percent to 20.5 cents.

BIOTA

Biota says Glaxosmithkline has reported Relenza sales of $27.1 million for the three months to September 30, 2008 with indicative royalties to Biota of $1.9 million.
The royalty payment follows the previous quarter indicative royalty of $400,000 and compares to indicative royalties of $5.4 million for three months to September 30, 2007 and $4.1 million for the three months to September 30, 2006. Biota's best quarter for indicative royalties was $16.0 million in the three months to March 31, 2007.
Biota fell 8.5 cents or 20.48 percent to 33 cents with 1.4 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell will expand its breeding capabilities with the construction of a designated pathogen-free facility for the breeding of its pig herd.
Living Cell said building consent has been granted for the facility, to be built in Invercargill in New Zealand's South Island and is expected to be operational by April 2009.
The company said the facility would allow it to expand its pig herd under conditions that maintain their high health status free of infectious organisms.
Living Cell said the facility complied with US Food and Drug Administration standards and animal welfare guidelines, providing living space for the pigs to interact socially with each other and staff, with a separate maternity unit provided for sows and piglets.
Living Cell's chief operating officer Dr Paul Tan said the facility was "integral to the company's future growth, given the recent approval for the initiation of a phase I/IIa clinical trial in New Zealand and the expansion of our Russian clinical trial which commenced in mid-2007 and has yielded positive safety and efficacy data to date".
"Porcine islet cells of uniform quality are critical to the administration of our clinical trials," Dr Tan said.
Living Cell climbed 0.5 cents or 2.63 percent to 19.5 cents.

PRIMA BIOMED

Prima says it has had "a positive pre-investigational new drug application meeting" with the US Food and Drug Administration.
Prima said the meeting in Washington DC on October 17, 2008 was "the end result of a stringent and rigorous assessment process" set to the highest regulatory standards.
The company said the focus of the meeting was Prima's plans for the commencement of phase II pivotal clinical trials in the US of its CVac therapy treatment for ovarian cancer.
Prima said it had clarified details of the development path for its CVac treatment, paving the way to file an investigation new drug application with the FDA. Minutes from the meeting are expected to be released by the FDA within 30 days, following which Prima will file its application, the company said.
Prima fell 0.1 cents or 11.11 percent to 0.8 cents.

VIRALYTICS

Viralytics has made a range of changes to its board and management, effective from the close of the annual general meeting on November 18, 2008.
Director Paul Hopper will become the independent non-executive chairman, while executive chairman and chief executive officer Bryan Dulhunty will become the managing director and CEO.
Viralytics said chief scientific officer and executive director Prof Darren Shafren would step down as executive director to focus fully on the chief scientific officer role.
The company said the changes would "significantly strengthen the company by enhancing good corporate governance and allowing executive management to more fully devote their time to operational goals".
The board will be Mr Hopper, Mr Dulhunty, non-executive director Peter Molloy and executive director of clinical affairs Dr Phillip Altman and the management team will be Mr Dulhunty, Dr Altman, CSO Prof Shafren and chief operations officer Stephen Goodall.
Viralytics has appointed Sarah Prince as company secretary effective immediately.
Ms Prince holds a BA and LLB and is a solicitor for Company Matters Pty Ltd.
Viralytics fell 0.1 cents or 1.96 percent to five cents.

RESONANCE

Resonance Health has appointed general manager Liza Dunne as managing director from today.

Resonance said Ms Dunne had worked for the company for more than five years in various roles covering almost every aspect of the business, including operations, quality, finance and marketing.

Ms Dunne has been the general manager for more than two years and since the resignation of the company's managing director in August 2007 has assumed many of the responsibilities of this role, the company said.

Resonance said its board "acknowledges the significant contribution Ms Dunne has made … and specifically her leadership since the company re-aligned its strategic direction to focus on further commercialization of the Ferriscan technology".

Prior to Resonance Health, Ms Dunne was a senior consultant with KPMG Consulting and held management positions with IBM.

Resonance was untraded at 0.9 cents.

IM MEDICAL

IM Medical shareholders will vote on the issue of 18.7 million shares to staff for termination pay and in lieu of payments and an 18.3 million share placement.

The IM Medical annual general meeting will consider the prior issue of 10,000,000 shares as termination pay to former chief executive officer Tommas Bonvino, 8,384,772 shares for consulting services and 315,586 to chief financial officer and acting CEO Roman Najdecki.

The meeting will also consider the prior issue of 18,324,230 placement shares at 0.81 cents along with the issue of 3,664,846 options with an exercise price of 0.9.

IM Medical shareholders will also consider the reelection of directors Dipak Sanghvi, Dr Leon Massage, Dr Ross Walker and Glenn Dalton.

The meeting will be held at Notice is given for the 2008 Annual General Meeting of the Company to be held in the Boardroom, Level 12, 484 St Kilda Road, Melbourne on November 19, 2008 at 9.30am.

IM Medical was unchanged at half a cent.