Biotech Daily

Thursday October 14, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: TISSUE THERA UP 15%; GENETIC TECH DOWN 13%**

*** PHARMAXIS CEO DR ALAN ROBERTSON RETURNS; APPROVALS CLOSE**

*** FDA ALCHEMIA FONDAPARINUX INSPECTION COULD SIGNAL APPROVAL**

*** WOOLWORTHS, FAIRFAX BOSS ROGER CORBETT JOINS HALCYGEN**

*** MESOBLAST BROADENS STEM CELL CANCER APPLICATIONS**

*** NUSEP FILES FORMULATION PATENTS**

*** PETER MACCALLUM PUBLIC LECTURE: CRACKING THE CANCER CODE**

*** PHYLOGICA APPOINTS NICK WOOLF CFO**

*** UBS INCREASES BUT DILUTED TO 5.5% OF ACUVAX**

MARKET REPORT

The Australian stock market was up 1.7 percent on Thursday October 14, 2010 with the S&P ASX 200 up 79.2 points to 4699.1 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and three were untraded. All three Big Caps fell.

Tissue Therapies was best, up 5.5 cents or 14.5 percent to 43.5 cents with 3.1 million shares traded, followed by Alchemia up 8.9 percent to 55 cents with 196,377 shares traded.

Virax climbed 7.7 percent; LBT and Living Cell were up more then six percent; Immuron and Patrys were up more than five percent; Prana was up four percent; Chemgenex and Viralytics rose more than three percent; with Acrux, Mesoblast, Pharmaxis and Sirtex up more than one percent.

Genetic Technologies led the falls, down 0.4 cents or 13.3 percent to 2.6 cents with 21,686 shares traded, followed by Benitec down 10 percent to 3.6 cents with two million shares traded.

Novogen lost 7.1 percent; Phosphagenics fell four percent; Heartware, Impedimed, Prima and Resmed were down more than three percent; Phylogica and QRX shed more than two percent; with Circadian down 1.6 percent.

PHARMAXIS

Pharmaxis says chief executive officer Dr Alan Robertson is back at work and Bronchitol is expected to be available in Europe for cystic fibrosis early in 2011.

Dr Robertson was admitted to hospital earlier this year (BD: Jun 18, 2010) and Pharmaxis said he was expected to resume full duties by the end of 2010.

Pharmaxis acting chief executive officer Gary Phillips told a teleconference that the US Food and Drug Administration approval for Aridol was a key milestone, demonstrating its ability to take a drug through four regulatory regimes, Bronchitol for cystic fibrosis was a larger market, with competitor Pulmozyne earning $US440 million a year.

Mr Phillips said the pre-new drug application with the FDA was expected by the end of 2010, and if all went well the application would be filed within nine months, with the FDA taking up to a year to give a response.

Mr Phillips said that the European Union was likely to make its decision by the end of 2010, and if positive, Bronchitol would be available in early next year with approval being decided in Australia about the same time.

Mr Phillips said the Aridol asthma test was expected to be launched in the US by April 2011 with reimbursement at a premium to the $50 cost per test.

Pharmaxis was up three cents or 1.15 percent to $2.65.

ALCHEMIA

Alchemia says the facility where syringes are filled with fondaparinux will be inspected by the US Food and Drug Administration in November.

The FDA accepted the fondaparinux (synthetic heparin) application from Dr Reddy's Laboratories last year (BD: May 11, 2009) and Alchemia said that the notice of acceptance meant that it would enter a period of formal review of six months from filing and hoped fondaparinux would be approved by the end of 2009.

Today Alchemia said the facility being inspected was the Hyderabad-based Gland Pharma which was FDA-approved and filled or finished products for the US market.

Alchemia said examination of the data on fondaparinux was part of a routine periodic inspection that would also include other drug products.

While not always required, FDA inspections regularly take place prior to the approval of products, Alchemia said.

"Whilst we can't predict the timing of final approval, we are encouraged by the progress of the [abbreviated new drug application] for fondaparinux at the FDA," Alchemia chief executive officer Dr Pete Smith said.

Alchemia was up 4.5 cents or 8.9 percent to 55 cents.

HALCYGEN PHARMACEUTICALS

Halcygen says former Woolworths chief executive officer and Fairfax Media chairman Roger Corbett will seek election as a director at the November 17 annual general meeting

Halcygen said Mr Corbett had "unparalleled retail and corporate experience" and had been responsible for the implementation of successful business acquisitions and strategic alliances, including the introduction of its Caltex Woolworths-branded petrol operations.

The company said Mr Corbett was the chairman of Fairfax Media which controlled newspapers, magazines, radio and digital media operating in Australia and New Zealand.

Halcygen said that in 2005, Mr Corbett was appointed a director of the Reserve Bank of Australia and in 2006, as a director of US-based Wal-Mart Stores Inc.

Halcygen was up 3.5 cents or 6.1 percent to 60.5 cents with 1.1 million shares traded.

MESOBLAST

Mesoblast says it is broadening the oncology applications of its off-the-shelf product for expansion of haematopoietic stem cells in patients with blood cancers.

Mesoblast said that following the clinical success of its mesenchymel precursor cell product for the expansion of cord blood, it would address new markets where expansion of haematopoietic stem cells could make a meaningful impact on clinical outcomes, including diseases such as multiple myeloma.

In July, Mesoblast said that of the first 25 patients transplanted with mesenchymal precursor cell-expanded haematopoietic progenitors from cord blood, “80 percent successfully achieved the key composite endpoint at 100 days of survival with sustained engraftment of both neutrophils and platelets” (BD: Jul 12, 2010). At that time, Mesoblast compared the result to the 38 percent rate for the composite endpoint achieved after transplantation with non-expanded cord blood in the US registry of 300 patients collected by the Center for International Blood and Marrow Transplant Research.

The phase Ib/II open-label clinical trial was conducted at the University of Texas MD Anderson Cancer Center and last year Mesoblast said that mid-trial results showed that its off-the-shelf mesenchymal precursor cells “expand haematopoietic stem cells in umbilical cord blood … 40-fold” (BD: Nov 6, 2009).

Today, Mesoblast said that more than 60,000 bone marrow transplants using haematopoietic stem cells were performed each year to rebuild the bone marrow of patients with cancers following high-dose chemotherapy.

The company said that cord blood expanded by its mesenchymel precursor cell product product addressed less than half of these and its new strategy would potentially target the entire bone marrow transplant market.

The company said that one major impediment to successful outcomes following bone marrow transplantation was the presence of residual cancer cells remaining in a patient's own bone marrow peripheral blood progenitor cells at the time of re-infusion.

Strategies that remove cancerous cells while expanding healthy haematopoietic stem cells in the peripheral blood progenitor cells prior to re-infusion had the potential to result in superior long-term outcomes.

In the University of Texas MD Anderson Cancer collaborative study led by Dr Yago Nieto and Prof Elizabeth Shpall, Mesoblast's product was used to achieve rapid and significant expansion of haematopoietic stem cells from the bone marrow peripheral blood progenitor cells of patients with multiple myeloma after residual cancer cells had been removed.

Mesoblast said new uses of its mesenchymal progenitor cell product for bone marrow transplantation would be developed under the existing US Food and Drug Administration orphan drug designation for expanding haematopoietic stem and progenitor cell numbers in patients with haematologic malignancies, such as multiple myeloma.

Mesoblast executive director Prof Silviu Itescu told Biotech Daily that the adult stem cell product could potentially be used for lymphomas as well as multiple myeloma.

Mesoblast said that Prof Shpall and her colleagues had been developing procedures for the ex-vivo expansion of haematopoietic stem cells.

“Mesoblast's cells have enabled us to generate the most promising expansion results to date,” Professor Shpall said.

“This will enable us to develop and test novel strategies to eliminate residual cancerous cells in the bone marrow of gravely ill patients, then expand their own haematopoietic progenitors to rebuild the bone marrow,” Prof Shpall said. “We hope that such strategies will improve the survival and cure rates of patients with life-threatening bone marrow cancers," Dr Shpall said.

Mesoblast was up three cents or 1.2 percent to $2.55.

NUSEP

Nusep says it has lodged two provisional Australian patents applications covering gel formulations for its Nuview gels.
Nusep said that the formulations significantly improved both the shelf life and separation quality of the Nuview gels, which were easily viewed under ultra-violet light, without costly and toxic stains to visualize the protein bands.
Nusep said the first commercial gel products using these new formulations would be launched in mid November 2010.
Nusep was up 1.5 cents or 5.9 percent to 27 cents.

PETER MACCALLUM CANCER CENTRE

The Peter MacCallum Cancer Centre says the 2010 Sir Peter MacCallum Public Lecture will discuss genomic research accelerating research discoveries and translating to cures.
Entitled 'Cracking the Cancer Code' the lecture will be given by the head of the Centre's genomic program and the Australian ovarian cancer study Prof David Bowtell and clinican researcher Dr Gillian Mitchell.
The Peter MacCallum Cancer Centre said Prof Bowtell would report on developments in genetic sequencing and international patient cohort studies that were leading to better understanding of the potential for personalized medicine and improved treatment.
The Centre said the Australian ovarian cancer study was the largest ovarian cancer study of its kind in the world.
The Centre said patient cohort studies provided an essential foundation resource as researchers work to understand inherited risk and genomic change in cancer cells.
The Peter MacCallum Cancer Centre said Dr Mitchell collaborated with Prof Bowtell on research into the identification of genetic mutations leading to increased cancer risk due to family history.
The Centre said Dr Mitchell would discuss issues related to genetic testing in the clinical environment and translating research findings into clinical practice.
Health advocate Dr Sally Cockburn will be the master of ceremonies for the lecture evening.
The annual Sir Peter MacCallum public lecture was established in 2009 as part of the 60th anniversary program celebrating the vision of Prof Peter MacCallum in establishing a specialist public cancer hospital and to provide an opportunity to report on developments in basic and translational research, as well as on recent advances in cancer treatment.
The lecture will be held at the Melbourne Town Hall, Swanston Street, Melbourne on October 21, 2010, from 7pm.
RSVP by email to: publiclecture@petermac.org or telephone: +613 9656 5258.
For further details of this lecture, visit www.petermac.org/Research.

PHYLOGICA

Phylogica has appointed executive director Nick Woolf as chief financial officer and vice-president of corporate development.
Phylogica said Mr Woolf would oversee the company's financial management, investor relations and capital markets interactions and would be actively involved with business development activities.
The company said the former chief business officer of Oxford Biomedica had extensive experience in international business development and finance.
Phylogica fell 0.1 cents or 2.1 percent to 4.6 cents.

ACUVAX

UBS AG has increased its investment in Acuvax from 51,470,000 shares (6.82%) to 51,980,000 shares but was diluted to 5.52 percent.

UBS AG said the holdings were held by its London Branch and related to a prime broking agreement.

Acuvax was untraded at 0.2 cents.