



Biotech Daily

Thursday November 10, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ANTISENSE UP 9%; GENETIC TECHNO DOWN 8%**
- * **STEM CELLS AUSTRALIA OPENS FOR BUSINESS**
- * **MESOBLAST CELLS REDUCE BLOOD SUGAR LEVELS IN MONKEYS**
- * **ST VINCENT'S APPROVES BPH, CORTICAL DYNAMICS TRIAL**
- * **HEALTHLINX EXPANDS GARVAN PROSTATE CANCER BIOMARKER TRIAL**
- * **ISONEA TO ISSUE US STOCK PRE-OTCQX LISTING**
- * **CBIO ACTION GROUP FOUNDERS DISBAND; CEASE SUBSTANTIAL**
- * **CHAIRMAN DR ZHUKOV PERVAN TAKES 21% OF ACTINOGEN**
- * **LBT DIRECTOR DR MIKE HIRSHORN RETIRES**

MARKET REPORT

The Australian stock market fell 2.35 percent on Thursday November 10, 2011 with the S&P ASX 200 down 102 points to 4,244.1 points.

Just five of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and seven were untraded.

Antisense was the best for the second trading day in a row, up 0.1 cents or 9.1 percent to 1.2 cents with 17.4 million shares traded.

Allied Health climbed 5.7 percent; Phylogica and Viralytics were up more than three percent; with Clinuvel and CSL up by less than one percent.

Genetic Technologies led the falls, down one cent or 7.7 percent to 12 cents, with 245,746 shares traded.

Benitec, Circadian, Impedimed and Mesoblast lost more than six percent; Living Cell and Prima were down more than five percent; Anteo and Neuren fell four percent or more; Acrux, Patrys, QRX and Starpharma were down more than three percent; Biota, Phosphagenics, Resmed and Universal Biosensors shed more than two percent; Alchemia was down 1.7 percent; with Cochlear, Pharmaxis and Sirtex down by less than one percent.

STEM CELLS AUSTRALIA

Stem Cells Australia has been established with \$21 million over seven years to fund and co-ordinate multi-disciplinary research work from eight leading research institutes.

Formally launching the collaboration, program leader Prof Martin Pera said the constituent organizations were the University of Melbourne, Monash University, the University of New South Wales, the University of Queensland, the Commonwealth Scientific and Industrial Research Organisation, the Walter and Eliza Hall Institute for Medical Research, the Florey Neuroscience Institutes and the Victor Chang Cardiac Research Institute.

Australian Research Council chief executive officer Prof Margaret Sheil said that as well as conducting research and educating the public, "Stem Cells Australia will take a leading role in encouraging public debate into the ethical, legal and public policy issues associated with stem cell science and technology".

Prof Pera said the consortium brought together scientists from many disciplines with a common goal of advancing stem cell research and regenerative medicine towards treatments for a range of currently incurable medical conditions.

"There is a great history of stem cell research in Australia," Prof Pera said. "[Prof] Don Metcalf at the Walter and Eliza Hall Institute was a pioneer in the field of blood stem cells, a system that serves as a paradigm for understanding stem cells in mammals, and this tradition carries forward today with [Prof] Doug Hilton and his associates who are part of our consortium," Prof Pera said.

"Some of the most important work in mesenchymal stem cells originated from Adelaide, which remains a leading center for this research," Prof Pera said.

"I was fortunate to contribute to the beginnings of human embryonic stem cell research when I was at Monash University and my colleagues there and elsewhere continue to make important contribution to this rapidly growing area," he said.

"Stem cell research has grown exponentially and we have witnessed many stunning breakthroughs: great improvement in our understanding of the molecular framework for pluripotency and technical advances in growing and manipulating pluripotent stem cells; new understanding of stem cells in adult tissues like the heart and brain and a better appreciation of their role in normal physiology and disease; induced pluripotency; and the first trials of cellular therapeutics made from human embryonic stem cells," Prof Pera said.

"There is much to do before this field realizes its full potential ... the early phase I trials of embryonic stem cell derived therapeutics are in a sense rudimentary and are liable to pose more problems and challenges than they solve," Prof Pera said. "Stem Cells Australia provides a great foundation for driving collaboration and innovation in this field."

"Our resources are limited, and we only represent a minority of the excellence in stem cell research across the country," Prof Pera said. "However, we are confident that we can build on this framework, to engage with our colleagues and to find pathways to translate our discoveries in several dimensions: in the research laboratories, into new technologies to study human functional genomics, to model human disease, and develop new medicines, and in the clinic, to deliver new cellular therapies," he said.

Prof Pera said the funding body, the Australia Research Council's "overarching demand is excellence in research and that will be our focus and our goal".

He said the governance council chair would be the former Victoria Governor, Prof David de Kretser, who was previously a professor of anatomy at Monash University and the associate dean for Biotechnology Development.

Prof Pera paid tribute to many people involved in fostering stem cell research including former Liberal Health Minister Kay Patterson, former Australian Democrats Senator Natasha Stott Despojer, along with Megan Munsie and Bob Williamson who campaigned for stem cell research and the preceding organization the Australian Stem Cell Centre.

MESOBLAST

Mesoblast says that a single injection of its adult stem cells significantly lowered blood sugar levels for up to eight weeks in non-human primates with type 2 diabetes.

Mesoblast said that the randomized, placebo-controlled study of 17 non-human primates with dietary-induced type 2 diabetes evaluated the effects of a single intravenous injection of its allogeneic, or off-the-shelf, mesenchymal precursor cells on blood glucose levels.

The company said that the lower blood sugar levels was accompanied by significant reductions in circulating inflammatory markers to levels associated with protection against heart attacks and death in patients with type 2 diabetes.

Mesoblast said that three control animals received a single saline injection, while four groups received one of four escalating doses of mesenchymal precursor cells at doses of 100,000 cells/kg, 300,000 cells/kg, 1 million cells/kg and 2 million cells/kg).

Mesoblast said that at baseline, the high mean fasting blood glucose levels were not significantly different between any of the type 2 diabetic groups.

The company said that during the eight week study, the control group showed no significant changes in fasting blood glucose levels, but a single injection of stem cells at each dose tested, significantly reduced fasting blood glucose levels as early as two weeks ($p < 0.001$ for each dose), with a clinically meaningful reduction in levels of up to 80 milligrams/deciliter (mg/dl) or 4.4 millimoles per litre (mmol/l) by four weeks.

Diabetes Australia's website says that the normal fasting range is 4-6 mmol/l (70-99 mg/dl) and the Mayo Clinic's website says up to 6.9 mmol/l (100-125mg/dl) is considered pre-diabetes, with 7 mmol/l (126mg/dl) on two separate tests confirming diabetes.

Mesoblast said the study showed a dose-dependent effect, with the highest three doses maintaining sustained reductions in fasting blood glucose over the entire eight week study period and the lowest dose the least effective.

The company said that over eight weeks, the 1 million and 2 million cells/kg groups maintained significantly lower mean fasting blood glucose levels compared with the control group (119 mg/dl and 110 mg/dl vs 154 mg/dl, both $p < 0.05$).

Mesoblast said that the mean fasting blood glucose level in the 300,000 cells/kg group (130 mg/dl) was moderately lower than the controls (154 mg/dl), while the lowest dose at 100,000 cells/kg was without effect (160 mg/dl vs 154 mg/dl).

The company said stem cell-treated subjects had a direct correlation between reductions in fasting blood glucose levels over time and reductions in circulating C-reactive protein (CRP), an inflammatory marker, predictive of risk for heart attack and cardiac death when present at levels more than 3mg/L in people with type 2 diabetes.

At eight weeks, mean CRP levels were 1.3 mg/L, 1.1 mg/L and 1.6 mg/L in the groups who received 300,000, 1 million and 2 million cells/kg, compared with 3.9 mg/L and 4.9 mg/L in the groups who received saline and 100,000 cells/kg, respectively ($p < 0.05$ for the pooled highest three doses vs pooled controls and lowest dose).

Mesoblast said an earlier study showed that a single dose of its stem cells injected into mice with diabetes resulted in a significant increase in blood insulin levels and sustained reduction in blood glucose levels for three weeks of follow-up, due to restoration in the damaged pancreas of the balance between insulin-producing beta cells, which reduce blood glucose, and glucagons-producing alpha cells, which increase blood glucose.

Mesoblast said type 2 diabetes would be the first indication to use its intravenous product, with a phase II human clinical trial expected to begin by April 2012

Mesoblast chief executive Prof Silviu Itescu said the company's cells had the potential "to establish a new medical paradigm for the treatment of type 2 diabetes which is safe and simultaneously targets multiple factors responsible for the disease and its complications".

Mesoblast fell 51 cents or 6.4 percent to \$7.50 with 1.6 million shares traded.

[BPH ENERGY](#)

BPH Energy says 3.6 percent investee company Cortical Dynamics has ethics approval from Melbourne's St Vincent's Hospital to trial its brain anaesthesia response monitor. BPH said the trial would study the monitor's ability to detect varying levels of anaesthetic agents in an operating room environment where the presence of multiple artifacts are known to complicate the electroencephalogram (EEG) assessment of anaesthetic action. The company said that St Vincent's senior staff anaesthetist Dr Desmond McGlade would be the principle investigator and that Cortical had worked closely with Dr McGlade and his team to develop protocols and reporting procedures.

BPH said the trial was expected to begin in December 2011.

The company said that a study at Swinburne University earlier this year concluded that all the signal gathering and analyzing components of the brain anaesthesia response (BAR) monitor were functioning correctly, providing the necessary verification for the BAR system to be used in the St Vincent's clinical trial.

BPH was unchanged at 3.3 cents.

[HEALTHLINX](#)

Healthlinx says the prostate cancer collaboration with the Garvan Institute of Medical Research will expand the patient cohort following positive results from the initial study. Healthlinx said the study aimed to assess the expression of proprietary biomarkers in plasma samples provided by the Garvan Institute, the relationship with chemotherapy and overall survival for sufferers of prostate cancer.

The company said the results "were promising".

Healthlinx managing director Nick Gatsios said the company was "extremely pleased with the results to date and we are looking forward to the ongoing collaboration with Garvan and the potential development of new markers to aid in prostate cancer prognosis".

The company said prostate cancer was the most common cancer diagnosed in Australia and the second greatest cause of cancer deaths in men.

Healthlinx fell 0.4 cents or 26.7 percent to 1.1 cents with 7.1 million shares traded.

[ISONEA \(FORMERLY KARMELSONIX\)](#)

Isonea says it has appointed the Bank of New York Mellon for its American Depositary Receipt program in preparation for its US listing on the OTCQX exchange.

Isonea said the trading symbol for Isonea would be ISOAY and through the over-the-counter quality excellence (OTCQX) listing, the company would provide a direct market for US investors.

The company said it was "the pioneer in acoustic respiratory monitoring (ARM) technology and software for disease management of asthma and related pulmonary disorders".

Isonea said its products had clearance from the US Food and Drug Administration, Australian Therapeutic Goods Administration and had Conformité Européenne (CE) mark approval.

Isonea chief executive officer Michael Thomas said that listing its ADR program on the OTC-QX was "a significant step for the continued transformation of the company".

Isonea was unchanged at 0.9 cents with 2.4 million shares traded.

CBIO

In September several trusts, funds and people combined to take a 5.5 percent stake in CBio, which led to a requisitioned meeting and board spill (BD: Sep 5; Nov 4, 8, 2011) Today, the group said it had ceased its collective substantial shareholding and reverted to individual holdings.

The September substantial shareholder notice said that Basildene Pty Ltd as trustee for Warren Brown & Associates became substantial in CBio with the acquisition of 8,818,049 shares or 5.5 percent of the company.

The September initial substantial shareholder notice said the holders included Warren Brown & Associates Superannuation Fund, Warren and Roslyn Brown, Retirewell Commercial Services for the Gillett Superannuation Fund, White turtle Pty Ltd, Pella Comino for the Pelagia Family Trust and Alan and Julie Baker for the Baker Family Trust. All gave their addresses as Queensland except for the Chifley Square Sydney-based White Turtle.

Today, Mr Tony Gillett told Biotech Daily that Mr Brown was one of the directors elected to the board and the group had achieved its primary aim of removing three directors, including chairman Stephen Jones.

Mr Gillett said the participants would all continue to retain their current CBio shareholdings and no one was contemplating selling any shares.

CBio fell one cent or 4.35 percent to 22 cents.

ACTINOGEN

Actinogen executive chairman Dr Zhukov (Zeke) Pervan has increased his holding in the company from 7,133,334 shares (14.42%) to 17,133,334 shares (21.29%).

Dr Pervan said he acquired the shares in consideration for shares in Celgenics, recently acquired by Actinogen (BD: Aug 26, Sep 26, Oct 4, 2011).

Actinogen was untraded at 4.5 cents.

LBT INNOVATIONS

LBT says director Dr Michael Hirshorn has advised the company that due to serious illness, he will not be seeking re-election at the annual general meeting.

LBT said Dr Hirshorn's retirement was effective immediately.

The company said it did not intend to put resolutions relating to his re-appointment or the grant of options to him to the meeting.

The company said Dr Hirshorn was appointed a director in January 2011.

LBT said it thanked Dr Hirshorn for his valuable commitment and contribution during this past year and give their very best wishes of support at this time.

Biotech Daily joins LBT in wishing Dr Hirshorn all the best and a speedy recovery.

LBT was unchanged at four cents.