



Biotech Daily

Tuesday November 22, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PRANA UP 19%; PSIVIDA DOWN 14%**
- * **MESOBLAST AGREES FDA PHASE II TYPE 2 DIABETES TRIAL DESIGN**
- * **FERMISCAN LOOKS TO A MINING SERVICES FUTURE**
- * **AUSTIN HEALTH APPROVES PRANA PHASE II PBT2 ALZHEIMER'S TRIAL**
- * **HEALTHLINX SIGNS ORYZON TO DISTRIBUTE OVPLEX IN SPAIN**
- * **FOUNDER ROB PHILLIPS WINS USCOM BOARD FIGHT**
- * **ORBIS BUYS 4.5m MORE STARPHARMA SHARES, TAKES 11%**
- * **ALLIED HEALTH APPOINTS BOB ATWILL CEO OF CELXCEL DIVISION**
- * **ANDREW KROGER REPLACES CRYOSITE CHAIRMAN THEO ONISFOROU**

MARKET REPORT

The Australian stock market fell 0.72 percent on Tuesday November 22, 2011 with the S&P ASX 200 down 30.0 points to 4,133.0 points.

Nine of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and eight were untraded.

Prana was the best, up three cents or 19.35 percent to 18.5 cents with 376,803 shares traded, followed by Optiscan up 14.3 percent to eight cents with 690,575 shares traded.

Antisense climbed 9.1 percent to 2.4 cents with 211.3 million shares traded; Anteo was up 3.3 percent; Biota, Clinuvel and Starpharma rose more than one percent; with CSL, QRX and Tissue Therapies up by less than one percent.

Psivida led the falls, down 18 cents or 13.7 percent to \$1.13 with 27,948 shares traded, followed by Impedimed down 10.9 percent to 57 cents with 7,572 shares traded.

Uscom lost 7.7 percent; Neuren was down 6.9 percent; Cellmid and Phylogica were down more than five percent; Mesoblast fell 4.3 percent; Nanosonics was down 3.2 percent; Bionomics, Universal Biosensors and Viralytics shed more than two percent; with Acrux, Cochlear and Resmed down one percent or more.

MESOBLAST

Mesoblast says it has agreed with the US Food and Drug Administration “key elements” of its first clinical trial using mesenchymal precursor cell in type 2 diabetes patients.

Mesoblast said that it would file an investigational new drug submission within the next 60 days for permission for patient recruitment to a randomized, placebo-controlled phase II trial comparing the effects of a single intravenous injection of one of three escalating doses of allogeneic or off-the-shelf mesenchymal precursor cells (MPCs) with placebo in patients with poorly-controlled type 2 diabetes.

The company said that the primary safety endpoint of the study would be at 12 weeks, and during this period patients would be evaluated for effectiveness of the treatment “in terms of blood glucose control and changes in various hormones that may be abnormal in patients with type 2 diabetes”.

Mesoblast said that the trial would monitor treatment-related changes in C-reactive protein, an established major predictor of cardiac arrest and death in type 2 diabetes patients.

Earlier this month, Mesoblast said 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 (BD: Nov 10, 2011).

Mesoblast said at that time, the treatment reduced the levels in cynomolgus (or Crab-eating macaque) monkeys from diabetic levels to pre-diabetic levels, but not to non-diabetic.

The company said the study demonstrated safety 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.

Today, Mesoblast said the doses to be tested as a single injection would be 300,000 MPC/kg, 1.0 million MPC/kg and 2.0 million MPC/kg, the same doses shown to produce a dose-dependent reduction in blood glucose levels in the cynomolgus monkey trial.

Mesoblast said it agreed with the FDA to extend the monkey study concurrent with the investigational new drug application in order to assess the durability of glucose-lowering effects following a single intravenous mesenchymal precursor cells injection and to evaluate the safety and effectiveness of repeat dose therapy.

The company said that in the US in 2010, there were 25.8 million people with diabetes or 8.3 percent of the population, of which 18.8 million people were diagnosed, seven million were undiagnosed and the total was expected to be more than 35 million in 2020.

Mesoblast fell 31 cents or 4.3 percent to \$6.95 with 1.1 million shares traded.

FERMISCAN

Fermiscan says that a review of business opportunities has determined that the mining services industry “presents a number of opportunities and a strong future”.

Over several years Fermiscan failed to commercialize Prof Veronica James’ x-ray diffraction test for breast cancer and acquired then sold the Sydney Breast Clinic and the rights to the intellectual property associated with the test.

The company recently raised funds for a number of purposes including further development of the breast cancer diagnostic (BD: Jan 16, Aug 3, 2011).

Fermiscan initiated a number of legal actions against Prof James, with the New South Wales Supreme Court finding in Prof James favor (BD: Jun 5, Nov,11, Dec 16, 2009).

Fermiscan has been in administration and returned to the ASX via a deed of company arrangement.

Fermiscan was unchanged at 1.2 cents with 5.8 million shares traded.

[PRANA BIOTECHNOLOGY](#)

Prana says the Austin Health Research Ethics Committee has approved a 40-patient, 12-month phase II imaging trial testing PBT2 for Alzheimer's disease.

Prana said the trial intended to measure physical changes in the brains of participants treated with PBT2 for 12 months and to consolidate the evidence over a longer period of the positive effects of PBT2 on patients' cognition reported in an earlier phase IIa.

Prana executive chairman Geoffrey Kempler said that PBT2 had been shown to significantly change amyloid beta levels in spinal fluid and improve the cognition of Alzheimer's disease patients in a 12 week trial.

"We believe that in this 12 month trial, PBT2 will establish its credentials as a safe and effective treatment for Alzheimer's disease," Mr Kempler said.

Prana said the double-blind, placebo-controlled trial would enroll 40 patients with prodromal or mild Alzheimer's disease at three sites in Melbourne and positron emission tomography imaging would be used to measure PBT2's effect on amyloid deposits in the brain and effects on increasing brain activity.

The company said that cognition effects would be measured by the neuropsychological test battery.

Prana said the trial received funding from the Alzheimer's Drug Discovery Foundation whose executive director Dr Howard Fillit said that PBT2 "stands out as one of the few remaining orally available agents with clinical trial evidence of cognitive benefit for Alzheimer's patients".

"Success in this trial will demonstrate target engagement by PBT2 in the brain of people with Alzheimer's disease and accelerate the clinical development of PBT2 to patients," Dr Fillit said.

Prana said that Alzheimer's disease affected more than 26 million people worldwide costing \$600 billion a year.

Prana was up three cents or 19.35 percent to 18.5 cents.

[HEALTHLINX](#)

Healthlinx says it has signed an agreement with Oryzon Genomics to distribute its Ovplex ovarian cancer test in Spain, with an option for Portugal, Andorra, France and Italy.

Healthlinx said it expected to execute the legal distribution agreement by early in the new year, with distribution to begin in Spain in 2012.

The company said Oryzon was based in Barcelona and was focused on the exploitation of biomarkers identified through genomics and proteomics in diagnostics, personalized medicine and therapy.

Healthlinx said Oryzon had four other diagnostic cancer biomarker tests for endometrial, colorectal, bladder and prostate cancer in development, with the endometrial cancer test due to be released by April 2012.

Healthlinx managing director Nick Gatsios said that Oryzon knew the biomarker space and early stage cancer diagnostic tests.

"Such knowledge means that the product will be marketed clearly and effectively to the right clinicians and gynecological oncologists, which should mean the women in Spain who are most at risk are aware and can use Ovplex from day one of sales," Mr Gatsios said.

Healthlinx said the market for ovarian cancer diagnostics in Spain was about 175,000 tests a year and with all jurisdictions combined was about 500,000 tests a year.

Healthlinx was up 0.1 cents or 9.1 percent to 1.2 cents with 3.3 million shares traded.

USCOM

Uscom's adjourned annual meeting has rolled executive chairman Philip Kiely and director Jochen Bonitz, while reelecting founder Rob Phillips and passing the remuneration report. The meeting was adjourned earlier this month, with a threat of internal legal action and the chairman's address attacking Mr Phillips (BD Nov 8, 2011).

The company said at that time that if Mr Phillips voted for the removal of Mr Kiely and Mr Bonitz and they were removed investors supporting the two "would take legal action against the company to recover funds previously subscribed".

Today, Uscom said that more than 14.7 million proxy votes opposed the reelection of Mr Kiely and Mr Bonitz with about 13 million proxy votes in favor.

Mr Phillips was reelected with more than 34 million proxy votes in favor and 9.5 million proxy votes against.

The remuneration report was passed overwhelmingly.

Uscom fell one cent or 7.7 percent to 12 cents.

STARPHARMA

Orbis Investment Management has increased its substantial holding in Starpharma from 23,151,172 shares (9.45%) to 27,663,167 shares (11.15%).

Orbis said it bought and sold Starpharma shares between March 28 and November 17 with the single largest transaction the acquisition of 1,981,715 shares for \$2,506,422 or an average price of \$1.265 a share.

In March Orbis sold 2,430,525 shares for \$2,628,530 or an average price of \$1.08 per share having acquired several million shares in Starpharma in 2010 at prices ranging from 50 cents to 63 cents a share and having become substantial with the acquisition of 18,244,802 shares at 48.5 cents a share in 2009 (BD: Nov 25, 2009; Mar 30, 2011). Starpharma was up two cents or 1.8 percent to \$1.15 with 1.5 million shares traded.

ALLIED HEALTHCARE GROUP

Allied Health has appointed Bob Atwill as the chief executive officer of its Celxcel tissue engineering division to commercialize its bovine patch for congenital heart disease. Earlier this year, Allied Medical merged with Biomd, which had been developing the Adapt-tissue engineering process-treated bovine cardiac patch Cardiocel to create Allied Health, which also has a hospital distribution and a 37.27 percent interest in vaccine developer Coridon (BD: Feb 19, 2009; May 19, 2011).

Today Allied said that Mr Atwill had more than 30 years experience in the pharmaceutical, biotechnology and healthcare sectors and had been a chief executive officer and senior corporate officer in US, UK and Australian companies.

Allied said that prior to his appointment to Celxcel, Mr Atwill was chief executive officer of Liquitab Systems and chief executive officer of Biogrid Australia, a secure, information technology platform and infrastructure providing access to clinical data, imaging and specimens.

The company said Mr Atwill had been consulting to Mesoblast and Biocomm Squared.

Allied said that Mr Atwill previously was the chief executive officer of Clinical Cell Culture, now Avita Medical, sales and marketing director of the Corn Group Plc and European managing director of the Sun Healthcare Group.

Mr Atwill has a Bachelor of Science degree in biochemistry for the University of Bristol and a Masters of Business Administration from Ashridge Business School in Hertfordshire, UK.

Allied Health was unchanged at 3.4 cents.

CRYOSITE

Cryosite says that Andrew Kroger has been appointed a non-executive director and replaced chairman Theo Onisforou.

The company said that “on the appointment of Mr Kroger, Mr Onisforou has elected to resign as a director of Cryosite”.

Last week, Cryosite shareholders defeated both the remuneration report and the re-election of director Theo Onisforou with more than nine million votes against both resolutions (BD: Nov 8, 2011).

Cryosite said at that time that the poll of votes showed 3,851,880 proxy votes in favor of the reelection of Mr Onisforou with 9,299,881 proxy votes against, while the cord blood storage company’s remuneration report was supported by 2,269,701 proxy votes, with 9,423,809 votes against.

The company reappointed Mr Onisforou as a director to fill a casual vacancy.

Today, Cryosite said Mr Kroger had a long-term interest in Cryosite as one of the original investors when it listed on the Australian Stock Exchange.

The company said that Mr Kroger had a career in law, stock-broking, gold mining and finance, had been a director of public companies and was a director of Strategic Pooled Development Limited, a listed investment fund.

Cryosite said Mr Onisforou retired from the company “he has nurtured from its early days in 2000, to its emergence as a mature organization that is a market leader in its core business activities”.

Cryosite was up one cent or 6.9 percent to 15.5 cents.