Biotech Daily

Thursday August 21, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: POLARTECHNICS UP 9%, NOVOGEN DOWN 6%**

*** FDA WARNING PROMPTS MESOBLAST PIVOTAL SPINAL FUSION TRIAL**

*** HEARTWARE IMPLANTS 1st US HEART PUMP; BARCLAYS TAKES 6%**

*** PROTEOME FOCUSES ON DIAGNOSTICS, EXITS THERAPEUTICS**

*** GBS VENTURES INCREASES TO 22% OF PORTLAND ORTHOPAEDIC**

*** AUSBIOTECH MEETS IN GEELONG**

MARKET REPORT

The Australian stock market retreated 1.0 percent on Thursday August 21, 2008 with the All Ordinaries down 47.9 points to 4,949.6 points.

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

Polartechnics was best, up one cent or 9.09 percent to 12 cents, followed by Peplin closing up eight percent to 54 cents having been up as much as 30 percent at 65 cents.

Alchemia climbed 5.26 percent; Psivida was up 4.76 percent; Clinuvel climbed 3.13 percent; Biota rose 2.14 percent; with Heartware, Mesoblast and Viralytics up more than one percent.

Novogen led the falls, down nine cents or 5.73 percent to $1.48, followed by Phylogica down 5.41 percent to seven cents.

Circadian and Optiscan fell more than four percent; Avexa, Cochlear and Neuren were down more than three percent; Prana and Ventracor shed more than two percent; with Acrux, Antisense and CSL down more than one percent.

MESOBLAST

Mesoblast says a US Food and Drug Administration warning on its main competitor's technology will accelerate its cervical spine fusion application process.

Mesoblast said in a media release to the ASX that the FDA provided a notification "alerting healthcare practitioners to reports of life-threatening complications associated with recombinant human bone morphogenetic protein (rhBMP) when used in the cervical spine".

The July 1, 2008 warning is at http://www.fda.gov/cdrh/safety/070108-rhbmp.html.

Mesoblast executive director Prof Silviu Itescu says the FDA warning, along with a Monash University trial of cervical fusion in sheep completed last week and early data from a phase II human clinical trial for lumbar spine fusion, has accelerated plans to seek FDA for approval a pivotal phase II/III cervical spine human trial for his company's allogeneic (off-the-shelf) adult stem cells.

Prof Itescu told Biotech Daily that Medtronic had $US800 million sales of bone morphogenetic protein "of which the vast majority is for spinal fusion". He said spinal fusion was 40 percent of off-label use for bone morphogenetic protein.

Prof Itescu said the material was used to encourage bone growth and was not present in his company's stem cell material.

The FDA describes the response to the protein as "life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine".

Symptoms include "difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area …and [patients] need to seek medical attention immediately at the first sign of an airway complication".

"The safety and effectiveness of rhBMP in the cervical spine have not been demonstrated and these products are not approved by FDA for this use," the FDA said.

Prof Itescu said Medtronic was the "number one competitor in the market" and although the safety results from the human lumbar spinal fusion trial were based on very low numbers there were no adverse events and Mesoblast was requesting the FDA expand approval for the trial from single centre to up to 10 sites in a multicentre trial.

Along with the cervical spine fusion safety data in sheep "we can take that data to the FDA now for a cervical spine phase II trial" Prof Itescu told Biotech Daily.

In its media release Mesoblast said its allogeneic cell therapy product was safe and highly effective in preclinical trials for inter-body fusion of the cervical spine in the neck.

"These results provide Mesoblast with a major clinical and commercial opportunity in light of the recent notification by the [FDA]," the company said.

Mesoblast quoted the FDA recommending "that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies".

"Given the limited treatment options available for patients in need of cervical fusion, Mesoblast believes that this clinical indication may provide an accelerated path to regulatory market approval of its product," the company said.

Mesoblast said the Monash University trial of 24 ewes showed its allogeneic stem cell therapy in cervical fusion to be safe and indicated "superior fusion outcomes".

"Significantly, no cell-related adverse events were noted at any time throughout the study," Mesoblast said. "Groups receiving either dose of Mesoblast's allogeneic cells had earlier and more robust fusion than the other groups."

"In view of the FDA notification concerning life threatening complications of rhBMP in cervical fusion, we are encouraged that the profile of our allogeneic cells in the cervical space may translate into a safe and effective clinical alternative," Prof Itescu said.

Mesoblast was up 1.5 cents or 1.17 percent to $1.295.

HEARTWARE

Heartware says its first US patient has been implanted with its left ventricular assist system at Washington Hospital Center in Washington, DC.

The company said this was the start of its US bridge-to-transplant clinical trial, in which 150 patients awaiting heart transplantation will be enrolled at up to 28 centers.

Heartware said its left ventricular assist system (LVAS) was a miniature blood pump designed to provide circulatory support for patients with advanced heart failure.

The company said it was placed adjacent to the patient's heart and was designed "to avoid potentially more complicated abdominal implantation".

The principal investigator at Washington Hospital Center was cardiologist Dr Leslie Miller and the surgery was performed by the hospital's surgical director of the heart failure program, Dr Steven Boyce.

Dr Boyce and Dr Miller said in a joint statement that they had been "closely watching Heartware's progress and have been impressed by the results from the international clinical trial" in which 40 patients had been enrolled in Europe and Australia. The doctors said surgery "was quick and without incident and the patient is recovering well".

"The novel configuration of the Heartware device together with its small size allow the pump to be implanted in the pericardial space, potentially reducing the risks associated with more extensive surgery," Drs Miller and Boyce said.

"The pump has one moving part, an impeller that utilizes a passive suspension system designed to minimize mechanical wear and friction while pumping," they said.

Heartware president and chief executive officer, Doug Godshall, said the start of the US clinical trial was "one of the most important milestones in the company's history".

Mr Godshall said Heartware expected additional centers to complete their internal review processes and begin enrolling patients over the next several months.

Separately, Barclays Group has become a substantial shareholder in Heartware with a holding of 18,957,292 shares or 6.11 percent of the company.

Barclays said the shares were acquired over the past four months at an average price of 57 cents a share.

Heartware was up one cent or 1.69 percent to 60 cents.

PROTEOME

Proteome says it will cease active efforts to develop and commercialize a therapeutic compound portfolio acquired in the 2005 merger with Eukarion Inc.

Proteome, chief executive officer Dr Jenny Harry said that the management team had focused on biomarker discovery and development "to produce a pipeline of diagnostic products based on the company's proprietary platform".

"Simply put, the Eukarion portfolio no longer fits with our corporate development strategy," Dr Harry said.

Research will continue through funding from the US government but operations in Proteome's Boston office will be closed within the next three months.

Proteome will retain full rights to the portfolio of assets which are anti-oxidant compounds for dermatological and neurological indications and will continue to consider out-licencing opportunities. The close of US operations will save $550,000 a year from February 2009.

Dr Harry said Proteome "must remain focused on allocating resources to leverage the progress made with our two near-term revenue generating programs" for tuberculosis and wheat tests to consolidate the company's role in developing point-of-need diagnostic tests for infectious and respiratory diseases.

Proteome was untraded at nine cents.

PORTLAND ORTHOPAEDIC

GBS Venture Partners has increased its substantial shareholding in Portland Orthopaedics from 21,796,541 shares (13.99%) to 53,796,541 shares (22.44%).
The 32,000,000 shares were bought for $800,000 or 2.5 cents a share on July 31 and August 1, 2008.
Portland Orthopaedics was unchanged at two cents.

AUSBIOTECH

Industry organization Ausbiotech is holding its annual Victorian conference in Geelong today and tomorrow.
Ausbiotech chief executive officer Dr Anna Lavelle said the 2008 “Bio-Forum” would see about 100 executives, scientists, investors and government representatives descend on Geelong.
“This year’s conference program focuses on the theme of ‘biotechnology means business’ and will include sessions discussing the economic state of the industry, the successes and failures of Victorian biotech companies and sessions to allow input from delegates about challenges and issues the industry is facing,” Dr Lavelle said.
“Victorian Government representatives will be presenting their recently released Innovation Statement and there will be a chance for participants to get involved in discussions about biotech policy directions,” she said.
“This is the second time Bio-Forum has been held in Geelong,” she said.
“It is an ideal background for this event, particularly given it is home to an important biotech cluster, Bio-Geelong, which includes Deakin University and Chemgenex,” Dr Lavelle said.
Guest speakers include Chemgenex chief operating officer Dr James Campbell, who is also the chair of Bio-Geelong, Deakin University’s Prof Andrew Parratt and the IB Australian Biosciences Fund investment manager Matt McNamara.
Dr Lavelle thanked the Victorian Government for its support of the local biotechnology industry and as the major partner for this year’s event.