Biotech Daily

Wednesday August 5, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRANA UP 26%, PHYLOGICA DOWN 7%**

*** MESOBLAST'S ANGIOBLAST BEGINS US CARDIAC STEM CELL TRIAL**

*** BIOTECH DAILY, AUSBIOTECH AND ASPERMONT**

*** GENESIS IN $1m RNAi COLLABORATION**

*** NOVOGEN LICENCES NV-128 TO MARSHALL EDWARDS FOR $1.8m+**

*** 'KEY' EUROPEAN PATENT FOR PRANA'S PBT2 FOR ALZHEIMER'S**

*** DISSENT AT PRIMA OPTIONS MEETING**

*** TRADE MINISTER SIMON CREAN OPENS PARNELL'S $15m FDA PLANT**

*** FLUOROTECHNICS APPOINTS LARS UTTERMAN DIRECTOR**

MARKET REPORT

The Australian stock market fell 1.04 percent on Wednesday August 5, 2009 with the S&P ASX 200 down 44.8 points to 4264.5 points.

Seven of the Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and six were untraded.

Prana was best, up 4.5 cents or 25.7 percent to 22 cents with 1.1 million shares traded, followed by Tissue Therapies up 6.7 percent to 24 cents.

Cochlear climbed 4.6 percent; Biota, CSL and Genera rose more than two percent; Novogen, Resmed and Universal Biosensors were up one percent or more; with Acrux up 0.42 percent.

Phylogica led the falls, down 0.4 cents or 6.8 percent to 5.5 cents with 600,000 shares traded, followed by Antisense down 0.2 cents or 5.3 percent to 3.6 cents.

Nanosonics and Tyrian lost more than four percent; Benitec, Optiscan, Psivida and Viralytics were down more than three percent; Cellestis, Labtech, Pharmaxis and Sirtex shed more than two percent; Alchemia, Clinuvel, Mesoblast, Peplin and Sunshine Heart were down more than one percent; with Circadian, Heartware and Progen down by less than one percent.

MESOBLAST

Mesoblast's US sister company Angioblast Systems has begun a phase II clinical trial to evaluate Revascor adult stem cells for end-stage heart failure patients.

Mesoblast said Angioblast would evaluate the safety and effectiveness of the off-the-shelf adult stem cell product at multiple medical centres in the US.

The company said the trial would involve 80 patients who were waiting to receive a heart transplant from an appropriate donor and are being kept alive by a left ventricular assist device manufactured by Thoratec.

Mesoblast owns about 40 percent of Angioblast.

The trial will evaluate whether injections into the damaged heart of either of two increasing doses of Revascor improve heart muscle function compared with control injections over a 60 day to 90 day period, potentially enabling the patient to have the left ventricular assist device removed and no longer require a heart transplant.

Mesoblast said the trial was being conducted under an investigational new drug submission cleared by the US Food and Drug Administration and was funded by a grant from the US National Institutes of Health.

Mesoblast said very few treatment modalities were available for patients with end-stage heart failure.

The company said heart transplantation was "not an option for the vast majority of these patients because of the great shortage in organ donors".

Mesoblast said a left ventricular assist device (LVAD) could temporarily keep end-stage heart failure patients alive while they waited for an appropriate organ donor, but could not improve function of the damaged heart to a level where a transplant was no longer necessary.

Mesoblast aid that if Revascor could improve heart muscle function in this patient population, it could result in a new therapy for large numbers of class IV heart failure patients without the need for a heart transplant.

The company said the trial would complement Angioblast's existing phase II program in class II-IV heart failure patients with less severe loss of heart muscle function who do not require either a left ventricular assist device or a heart transplant.

Mesoblast said interim results from that trial showed that patients with the most severe loss of heart muscle function demonstrated the greatest recovery over a three-month period after receiving a single, lowest-dose of Revascor.

The company said the initial results formed the basis for testing Revascor in those class IV patients with the worst decline in heart muscle function, requiring LVAD support.

Mesoblast and Angioblast executive director Prof Silviu Itescu said that if his companies' technology could improve heart muscle function to a level where the LVAD support could be removed without the need for a heart transplant "we will have changed the treatment paradigm for this most severe group of heart failure patients".

Mesoblast said congestive heart failure was a leading cause of hospital admissions, morbidity and mortality in the Western world.

The company said there were more than five million people in the US suffering from congestive heart failure, with more than 550,000 new cases each year.

Mesoblast said heart failure was responsible for about 1.1 million hospitalizations in the US alone each year and 300,000 deaths with total direct costs of more than $US33 billion a year.

Mesoblast said Revascor was an allogeneic or off-the-shelf cell therapy product being developed to reverse congestive heart failure by rebuilding both blood vessels and heart muscle.

Mesoblast fell 1.5 cents or 1.25 percent to $1.185.

BIOTECH DAILY

Biotech Daily is pleased to learn that Aspermont and Ausbiotech have formalized a commercial joint venture. Aspermont publishes Australian Biotechnology News.

Along with other publications conducting commercial ventures that create potential conflicts of interest in reporting standards, this initiative leaves Biotech Daily as the only truly independent and dedicated publication informing the life sciences sector.

Separate to the Aspermont-Ausbiotech arrangement, there is a principle in professional journalism that reporters do not undertake paid work for those on whom they report.

It is an old-fashioned value often missing at daily newspapers across the world.

When Biotech Daily's analyst Marc Sinatra undertakes work for a private client, he is barred from writing about that company for two years.

It is simply not 'independent' to be paid by a company and then claim reporting on that company is objective.

Biotech Daily provides free advice to subscribers and operates a confidential match-making service requiring payment of one bottle of Australian champagne if a deal is struck.

Biotech Daily's broad subscription base makes it beholden to no individual interest and we are free to report without fear or favor, something that very few mainstream publications can claim.

The arrival of Ausbiotech's arrangement with Aspermont effectively leaves Biotech Daily as the only source of comprehensive, independent information about our sector.

It would not be possible without you, our subscribers.

David Langsam, Editor

GENESIS RESEARCH AND DEVELOPMENT

Genesis says a Japanese based investment fund will provide up to $1 million to establish and fund a new subsidiary company to develop its gene silencing technology.
Genesis said funding had been provided to pay Genesis for contract research services undertaken for the subsidiary.
The company said the investment fund would provide progressive funding of the subsidiary of up to $1 million and Genesis would transfer all its intellectual property and patent rights relating to RNA interference (RNAi) and the new single stranded gene silencing technology to the new subsidiary, named Solirna Biosciences.
Genesis said soli was the plural of solo recognizing the delivery of dual single strands of RNA to achieve gene inhibition through the RNAi mechanism (BD: Feb 18, 2009).
Genesis chief executive Stephen Hall told Biotech Daily that his company would own more than 50 percent of Solirna.
In a media release to the ASX Mr Hall said "a number of international groups have shown significant interest in this new technology" and said the transaction required finalization of documentation and approval of Genesis shareholders at a special meeting in September.
Genesis was untraded at 4.3 cents.

NOVOGEN

Novogen says its 70 percent US subsidiary Marshall Edwards will develop and commercialize the oncology compound NV-128.

Novogen said NV-128 was an anti-cancer compound which, in pre-clinical studies, showed that it promoted cancer cell death in multi–drug resistant cancer cells by inducing caspase-independent DNA degradation and cancer cell death via the AKT-mTOR pathway.

Novogen's managing director Christopher Naughton told Biotech Daily that the research work would continue in both Australia and the US.

Novogen's media release to the ASX said the licence consisted of a single upfront payment to Novogen of $US1.5million ($A1.78 million) and payments for reaching the milestones of US investigational new drug approval, entering phases II and III trials and receipt of a new drug application for marketing and a royalty on sales of five percent.

Novogen said Marshall Edwards would fund the clinical programs and was responsible for the commercial development of the drug.

Novogen said Marshall Edwards had concluded recruitment in the phase III trial of phenoxodiol for chemotherapy-resistant ovarian cancer and had received approval from the FDA to trial triphendiol in the US for pancreatic cancer and cholangiocarcinoma.

Triphendiol has FDA orphan drug status for these indications and late stage melanoma.

Marshall Edwards chairman Prof Bryan Williams said the in-licencing of the mTOR inhibitor NV-128 was "an exciting extension" to the company's portfolio.

"NV-128 has a different mode of action to our current drug candidates and its advantages over other mTOR inhibitors auger well for an exciting and valuable addition to the pharmaceutical armamentarium of new cancer treatments," Prof Williams said.

Novogen said NV-128 did not rely on traditional caspase-mediated apoptosis, a death mechanism is not effective in cancer cells that have become resistant to chemotherapy.

The company said NV-128 uncoupled a signal transduction cascade which had a key role in driving protein translation and uncontrolled cancer cell proliferation and NV-128 induced mitochondrial depolarization via the novel mTOR pathway.

Novogen said that in cancer cells, mTOR signals enhance tumor growth and may be associated with resistance to conventional therapies.

Inhibition of the mTOR pathway appeared to shut down many of these survival pathways, including proteins that protect the mitochondria of cancer cells.

Novogen was up 1.5 cents or 1.95 percent to 78.5 cents.

PRANA

Prana says the European Patent Office has granted a key patent for PBT2 entitled '8-Hydroxyquinoline derivatives'.

Prana said the patent covered the composition of matter of selected families of 8-hydroxyquinoline compounds including PBT2 and the uses of such compounds for the treatment of neurological diseases, such as Alzheimer's and Huntington's diseases.

Prana said the European patent had a 20 year term to July 16, 2023, with a possible extension of term of up to five years under supplementary protection provisions.

Prana's said PBT was its lead Alzheimer's disease compound and had completed a phase IIa study in early Alzheimer's disease patients demonstrating safety and tolerability.

The company said PBT2 showed improvement in executive function, an important aspect of cognitive performance and reduced the levels of Abeta in the spinal fluid of patients.

Abeta is a key protein associated with Alzheimer's disease.

Prana climbed 4.5 cents or 25.7 percent to 22 cents with 1.1 million shares traded.

PRIMA

Up to 18.8 percent of proxy votes opposed the issue of options to Prima directors Ata Gokyildirim, Dr Richard Hammel and Martin Rogers.
All three resolutions were passed overwhelmingly with more than 27.3 million proxy votes in favor and more than 6.3 million proxy votes against.
More than two million proxy votes abstained, with 709,900 proxy votes undirected.
Prima said the resolutions were postponed "following shareholder feedback …to allow sufficient time to distribute additional information for shareholders consideration" (BD: May 22; Jun 25, 2009).
Prima fell 0.2 cents or 2.74 percent to 7.1 cents with 3.5 million shares traded.

PARNELL

The Federal Minister for Trade Simon Crean has opened Parnell's new $15 million veterinary pharmaceuticals manufacturing plant and laboratories.
A media release from Parnell said the 3,000 square metre plant in Alexandria, New South Wales, was licenced to manufacture "highly potent sterile injectables" for sale in Europe and the US.
Mr Crean said the facility was "a great success story and we are helping Australian companies like Parnell to fight above their weight in export markets".
He said the Export Finance and Insurance Corporation was "the bridge between Australian companies and the banks".
"There has been a huge gap over the last 18 months between companies and their banks, with the financing of projects like the Parnell facility simply not possible in the credit conditions without EFIC's involvement," Mr Crean said.
Parnell said it was "a world leader in veterinary pharmaceuticals" and the Australian Therapeutic Goods Administration and US Food and Drug Administration approved facility was a significant investment for Parnell.
Parnell is a private company.

FLUOROTECHNICS

Fluorotechnics has appointed Lars Utterman as a nonexecutive director.
Fluorotechnics said Mr Utterman had more than 30 years sales and general management experience with biotechnology companies.
The company said Mr Utterman was the chief executive officer of the German-based Iongate Biosciences, a company specializing in developing systems for transporter protein measurements in drug discovery.
Mr Utterman is also chairman three Swedish companies.
Fluorotechnics said Mr Utterman held a Master of Science in chemical technology and a bachelor's degree in business administration.
Fluorotechnics was untraded at 40 cents.