Biotech Daily

Thursday June 5, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN:**
PORTLAND UP 17%, STEM CELL, CYTOPIA DOWN 17%

*** FDA CLEARS MESOBLAST, ANGIOBLAST PHASE II CARDIAC TRIAL**

*** LIVING CELL EXPANDS DIABETES TRIAL TO HIGHER DOSE**

*** ARANA COMPLETES 2nd CSL PROJECT**

*** EUROPEAN PATENT FOR STEM CELL MEDIA**

*** ANADIS SHARE PLAN RAISES $823k**

MARKET REPORT

The Australian stock market fell 1.1 percent on Thursday June 5, 2008 with the All Ordinaries down 64.4 points to 5,633.8 points.

Twelve of the Biotech Daily Top 40 stocks were up, 21 fell, five were unchanged and two were untraded.

Portland was best, up half a cent or 16.67 percent to 3.5 cents on modest volumes, followed by Avexa up 13.11 percent to 34.5 cents with 2.2 million shares traded and Proteome up 12 percent to 14 cents.

Phosphagenics climbed 9.09 percent; Alchemia was up 7.04 percent; Mesoblast climbed 5.75 percent; Progen and Resmed were up more than four percent; Living Cell climbed 3.33 percent; Benitec rose 2.41 percent; with Biota and Cellestis up more than one percent.

Cytopia and Stem Cell led the falls, both down 16.67 percent to 25 cents and 30 cents, respectively, followed by Universal Biosensors down 8.6 percent to 85 cents.

Phylogica, Starpharma, Tissue Therapies and Ventracor lost more than seven percent; Sunshine Heart was down 5.33 percent; Antisense, Optiscan and Psivida fell more than four percent; Heartware, Neuren and Polartechnics were down more than three percent; with Acrux, Agenix, Bionomics, Chemgenex; Peplin and Sirtex down more than one percent.

MESOBLAST

Mesoblast says its US sister company Angioblast has regulatory approval to begin a phase II trial of its stem cell therapy for patients with congestive heart failure.

Mesoblast said the US Food and Drug Administration had cleared an investigational new drug submission and the multiple centre trial will enroll 60 patients with congestive heart failure.

Fifteen patients will serve as controls and 45 will receive one of three doses of the company's patented allogeneic or off-the-shelf adult stem cells.

Study endpoints will include measurement of heart muscle function and improvement in heart failure symptoms at six and 12 months.

Mesoblast said the patented allogeneic cells would be injected into damaged heart muscle by cardiac catheter, in a similar way to the company's ongoing phase II trial in patients with acute myocardial infarctions (heart attacks).

The company said cardiac catheter technology would be provided through a collaboration with the Johnson & Johnson companies Cordis Corp and Biosense Webster.

In parallel with the phase II trial, Angioblast will continue its preclinical collaboration with Abbott to jointly develop a heart failure product.

The company expects that the results of both the phase II clinical trial and its preclinical collaboration will support the subsequent filing of a pivotal, phase IIb/III clinical trial.

Mesoblast said that in an Australian pilot trial last year, injection of the company's autologous cells (patients' own cells) resulted in an improvement in heart muscle function and reduced symptoms of both heart failure and severe angina (see Biotech Daily August 10, 2007).

Additionally, the company's allogeneic cells have been shown to improve heart muscle function and reverse established heart failure in preclinical trials.

The founder and chief scientist of both Angioblast and Mesoblast Prof Silviu Itescu said that obtaining rapid FDA clearance to begin a phase II trial of allogeneic cells in patients with heart failure “confirms the robustness of the clinical and preclinical results of the platform adult stem cell technology”.

“Treatment of heart failure is a major unmet clinical need and a huge commercial opportunity for us,” Prof Itescu said.

“If our initial clinical and preclinical results are mirrored in this phase II trial, we will have a unique and highly effective product for this massive and growing market,” Prof Itescu said.

Mesoblast said heart failure was a leading cause of death in the developed world, estimated to affect more than 11 million people worldwide.

In the US alone, nearly 5 million patients suffer from heart failure, making this condition a major cause of total hospitalizations, chronic disability, and mortality, Mesoblast said.

Mesoblast each year in the US 550,000 new cases are diagnosed and some 300,000 patients die because of the progressive condition.

The majority of heart failure patients have underlying cardiovascular disorders that are often the precursors of their condition.

The most common of these are atherosclerosis, myocardial infarction, hypertension, cardiomyopathy and arrhythmia.

Mesoblast climbed five cents or 5.75 percent to 92 cents.

LIVING CELL TECHNOLOGIES

Living Cell says that positive preliminary data from its first clinical trial of Diabecell for type 1 diabetes has encouraged an expansion of the trial and to test higher doses.

Living Cell said that in its first phase I/IIa trial of the Diabecell encapsulated porcine insulin producing cells, five patients were implanted with the lowest dose.

The company's said on March 31, 2008 that there were no significant adverse effects and a clinical effect was demonstrated with reduction in daily insulin requirement for up to six months follow up with satisfactory control of blood glucose.

Living Cell medical director Prof Bob Elliott said the clinical effects observed with the lowest dose and the uncomplicated safety profile to date "have encouraged our clinical experts in Moscow to implant higher doses with the expectation of greater clinical benefit".

Living Cell chief executive officer Dr Paul Tan said the scientific and ethics approvals allowed the trial protocol to be revised and continued with the total number of patients increased from six to 10 at this stage.

"In subsequent implants, the dose of Diabecell will move up from 5,000 islet equivalents per kilogram body weight (IEQ/kg) to 10,000 IEQ/kg. This revision of the clinical protocol in Moscow in effect expedites our clinical program for Diabecell," Dr Tan said

Living Cell was up one cent or 3.33 percent to 31 cents.

ARANA

Arana says it has completed a second collaborative project to develop humanized antibodies with partner CSL.

Arana said the provision of the final report triggers a payment from CSL and CSL would confirm the results.

Arana said it used its Superhumanization technology to develop humanized versions of a lead antibody from the CSL pharmaceutical pipeline.

The humanized products have been further optimized using Arana's Evogene technology.

Should CSL choose to develop one of these antibodies through clinical testing, Arana will be eligible to earn milestone payments and will earn royalty payments on the sale of all marketed products.

Arana chief executive officer Dr John Chiplin said the "successful engineering of another biopharmaceutical product for our partner CSL clearly demonstrates the quality of our technology platform, validates the Arana business model of creating revenues from our platform technologies and shows that we can consistently deliver results to our pharmaceutical partners".

"We look forward to improving additional products for our partners as we move the business forward," Dr Chiplin said.

Arana said the project was "the third partnered product that has been successfully engineered to date".

The company said engineering of the first CSL product was announced in November 2007. In March 2007 Arana announced successful validation of its first project with Glaxosmithkline.

In August 2007 Arana said it had begun a second project with Glaxosmithkline on a lead product from the pharmaceutical company's pipeline.

Arana said it was using its technology platform to develop protein therapeutics both internally, as well as in further collaborations with Melbourne-based Vegenics and through an alliance with US-based Aveo Pharmaceuticals, which is using Arana's Superhumanization technology for the internal development of several products.

Arana was unchanged at $1.06 with 1.4 million shares traded.

STEM CELL SCIENCES

The European Patent Office has granted Stem Cell Sciences a patent protecting its existing range of embryonic stem cell culture media.

Stem Cell said the media were marketed in Europe under the brands Hescgro and Escgro and were used in the culture of human and mouse embryonic stem cells, respectively.

The company said the patent covered cell culture media that use a combination of signaling molecules called bone morphogenetic protein (BMP) and leukaemia inhibitory factor (LIF).

Stem Cell Sciences said its media products could be used to culture both human and mouse embryonic stem cells without the use of animal serum.

To meet the higher control requirements of human cell culture, Hescgro was fully-defined and free from animal components.

Stem Cell Sciences chief scientific officer Dr Tim Allsopp said the availability of serum-free and fully defined media was "of vital importance" in cultivating embryonic stem cells.

"In many applications of human stem cell technology, such as the production of human therapeutics, the use of animal products is deemed unacceptable by the clinical community and regulatory authorities," Dr Allsopp said.

"In all stem cell research, the use of serum is highly undesirable, because serum contains signaling molecules that can cause stem cells to differentiate," he said.

"This process of differentiation is uncontrollable and irreversible and neutralizes the very advantage that a naturally replenishing culture of stem cells is meant to provide," Dr Allsopp said.

Stem Cell Sciences chief executive officer Dr Alastair Riddell said the increasing use of stem cells in drug discovery had created "a strongly growing demand for high quality cell culture media products".

Stem Cell Sciences has granted a licence to Millipore to produce and distribute its Hescgro and Escgro products.

Stem Cell Sciences fell six cents or 16.67 percent to 30 cents.

ANADIS

Anadis says its share purchase plan was oversubscribed and raised $823,000.

The company said the plan was originally limited to $750,000, but "due to an overwhelming support on the final day of the offering, the directors decided that it would not be appropriate to prevent some shareholders from participating in this opportunity".

Anadis chief executive officer Dr Zeil Rosenberg said the funds would accelerate plans to commercialize the company's products, including development of new clinical trials, to improve human health and create shareholder value.

Anadis was unchanged at five cents.