Biotech Daily

Thursday May 14, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 16%, GENETIC TECHNO DOWN 22%**

*** MESOBLAST CLAIMS EARLY STEM CELL SUCCESS IN HEART FAILURE**

*** OPTISCAN RAISES $500k, NEW ZEISS DEAL, MAJOR BOARD CHANGES**

*** FDA ACCEPTS PHARMAXIS' ARIDOL APPLICATION**

*** METABOLIC: LAURENT FOSSAERT POLYNOVO CEO; WAY FORWARD**

*** STIRLING ADDS AIDS TO TB, SWINE FLU AS IMMUNOXEL SUCCESSES**

*** CEPHALON TAKES 41.6% OF ARANA**

MARKET REPORT

The Australian stock market fell 3.44 percent on Thursday May 14, 2009 with the S&P ASX 200 down 132.7 points to 3,723.4 points.

Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and seven were untraded.

Antisense was best, up half a cent or 15.6 percent to 3.7 cents with 38,500 shares traded, followed by Benitec up 8.3 percent to 3.9 cents.

Universal Biosensors climbed 7.2 percent; Bionomics, Genera and Polartechnics were up more than four percent; Biota, Clinuvel and Psivida were up more than one percent; with Arana, Cochlear and Sirtex up by less than one percent.

Genetic Technologies led the falls, down 1.2 cents or 21.8 percent to 4.3 cents with 12,300 shares traded, followed by Living Cell down 9.1 percent to 20 cents.

Cellestis lost 6.7 percent; Nanosonics was down 5.6 percent; Progen fell 4.9 percent; Labtech lost 3.7 percent; Acrux, Alchemia, Chemgenex, Pharmaxis and Tyrian shed more than two percent; Novogen and Heartware fell more than one percent; with CSL Peplin and Resmed down by less than one percent.

MESOBLAST

Mesoblast says a single injection of its Revascor adult stem cell product improved heart muscle function on patients with moderate to severe congestive heart failure.

Mesoblast said that three-months after receiving a single injection into damaged heart muscle of the lowest dose of its allogeneic or off-the-shelf stem cell product Revascor patients “demonstrated significantly improved heart muscle function”.

The company said Revascor was being developed to reverse congestive heart failure by rebuilding both blood vessels and heart muscle.

Mesoblast said the interim efficacy results came from the first 20 patients in its randomized, placebo-controlled phase II trial being run at multiple centres in the US by its sister company Angioblast.

The trial aims to compare one of three increasing doses of Revascor against standard of care in up to 60 patients suffering from moderate to severe congestive heart failure, defined as a baseline ejection fraction 40 percent or lower by echocardiogram.

Mesoblast said that “on the basis of the positive interim efficacy results and the excellent safety profile seen to date” in patients receiving the lowest dose of Revascor, the second group of patients to receive the next higher dose was being recruited.

In the first 20-patient cohort, 15 were randomized to receive the lowest dose of Revascor and five were randomized to the control arm.

Control patients with baseline ejection fraction (of blood from the left ventricle) 40 percent or below demonstrated an 11 percent mean decrease in ejection fraction over the first three months from 31 to 27 percent.

Patients with baseline ejection fraction 40 or below who received a single injection into damaged heart muscle showed a 37 percent mean increase in ejection fraction over the period (mean values increased from 28 to 37 percent; $p=0.017$).

The 10-point mean difference in absolute ejection fraction at three months between cell-treated and control patients was significant ($p<0.05$).

Patients with the most severe and advanced heart failure, defined as a baseline ejection fraction of less than 30 percent of which nine patients were treated with Revascor, had an even greater improvement in heart function, with mean increase in ejection fraction over three months of 50 percent ($p=0.02$).

Mesoblast executive director Prof Silviu Itescu said he was “very encouraged” by the three-month interim efficacy results.

“We eagerly await the six month results to see whether these effects are sustained or even further augmented,” Prof Itescu said. “If the clinical trial continues to parallel our pre-clinical results, we anticipate even better outcomes in the next group of patients receiving a higher dose of Revascor.”

The director of Monash University’s Centre of Cardiovascular Research and Education in Therapeutics Prof Henry Krum said the initial results were “very exciting”.

“Equally as important is the lack of any safety concerns to date, meaning that for the first time we could potentially have a safe and effective off-the-shelf cell therapy product which could change the treatment paradigm for patients with chronic heart failure,” Prof Krum said.

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

There are more than five million people in the US with congestive heart failure, with more than 550,000 new cases annually. Despite advances in prevention and treatment, heart failure is responsible for about 1.1 million hospitalizations in the US alone each year and about 300,000 deaths with total direct costs in the US exceed $US33 billion a year.

Mesoblast was unchanged at 77 cents with 2.9 million shares traded.

OPTISCAN IMAGING

Optiscan says it has signed a new contract with Carl Zeiss, closed a $500,000 convertible note, restructured and reduced cost base and has shed two directors.

Optiscan said Angus Holt had been appointed chairman from today, while directors Grant Latta and Tony Rogers had resigned.

The board consists of Angus Holt, chief executive officer Vicki Tutungi and Peter Delaney.

Optiscan said it had funding for 12 months and the changes along with a new strategy meant it could capitalize on the growing medical market in endo-microscopy, which it pioneered.

Optiscan said it began its collaboration with Germany's Carl Zeiss Group in July 2008 and the new contract has up-front and regular milestone payments over the next 12 months.

The company said the parties would work together to complete an extensive second human trial of the technology building on "the encouraging interim results from the first human trial".

Optiscan said it had completed a private placement of 10 million convertible notes, at five cents each, raising $500,000.

The company said the convertible notes were secured and mature on May 12, 2012.

They can be converted at face value or the 90 day trading average of the share price at the holder's election from May 12, 2010, with early conversion in limited circumstances.

The placement does not require shareholder approval, but Optiscan said it might seek shareholder approval to ratify the placement at its next general meeting.

Optiscan said it had "embarked on a substantial cost cutting program" and the total cost base was 50 percent of what it was 12 months ago and employs 14 people.

The restructuring was in response to both the tightening of capital markets, particularly in the small cap arena and also to the expiration of the manufacturing contract with Pentax Hoya.

Until the end of March 2009 Optiscan was manufacturing the ISC 1000 product for Hoya.

Hoya may now manufacture the device itself and pay Optiscan a royalty.

Optiscan said it would continue with Zeiss while furthering near-term development of a second generation product for gastroenterology, until recently a field held exclusively by Hoya.

Optiscan said it had undertaken significant development work into "many other applications for its technology and products with promising results".

Areas of development include robotic surgery with a focus on prostate cancer; women's health with a focus on endometriosis; and general surgery including liver and pancreas.

Consistent with its focus on Zeiss and a second generation product, Optiscan said it would "devote minimal resources to these other developmental areas over the next 12 months" which would be revisited where it was neither a drain on finances nor management focus.

Following the termination of the exclusive agreement with Hoya for the technology in gastroenterology, Optiscan said it was focused on releasing a second generation product for gastroenterology and was looking for new commercial partners.

Optiscan said it had a new prototype platform and was building the clinical prototype for a short trial to demonstrate the second generation product's significant new features.

Based on cash reserves, projected revenues from contracts and product sales, and stringent cost control, the company said it had "sufficient funds for at least the next 12 months".

Optiscan was unchanged at 4.6 cents.

PHARMAXIS

The US Food and Drug Administration has accepted for standard review Pharmaxis' new drug application for its Aridol mannitol bronchial challenge test.

Pharmaxis said the FDA would advise the company of the result of the review on December 27, 2009.

Pharmaxis said it was seeking approval for Aridol for "the assessment of bronchial hyper-responsiveness to aid in the diagnosis of patients with symptoms of or suggestive of asthma".

The company said asthma affected more than 34 million people in the US with an annual economic cost of $US19.7 billion and when approved, Aridol would be the first dry powder bronchial challenge test available in the US.

Pharmaxis chief executive officer Dr Alan Robertson said the company had been "greatly encouraged by the interest respiratory physicians have shown in Aridol at recent US scientific conferences".

"We estimate that 200,000 bronchial hyper-responsiveness tests are performed in the US each year and hope that the introduction of a dry powder test kit will encourage more physicians to utilize this test when diagnosing asthma," Dr Robertson said.

Aridol is approved for sale in Europe, Australia and Korea and has been included in the Global Initiative for Asthma guidelines and in the US Asthma Management Guidelines.

Pharmaxis fell six cents or 2.34 percent to $2.50.

METABOLIC, POLYNOVO

Metabolic says Laurent Fossaert has been appointed acting chief executive officer of Polynovo and outlined changes to the two companies.

Metabolic said Mr Fossaert joined Polynovo in June 2007 and had been the company's chief operations officer. He is a polymer and process engineer with significant experience in the medical device and polymer industries.

Metabolic said its main focus was to conserve cash as best as possible with a net cash balance of $11.5 million and a "medium term objective of seeking an appropriate investment opportunity".

To further reduce operating costs the chairman's fees will be cut from $90,000 to $65,000 a year and non-executive directors fees reduced from $45,000 to $40,000 a year.

Metabolic said it was the intention to reduce the board to four directors in the medium term.

A review of legacy assets within the company including the compound AOD9604 for obesity would be undertaken to evaluate the commercial potential of these assets, to conclude by July 31, 2009.

Metabolic said Polynovo had "an exciting polymer-based technology" with many potential applications.

"We believe Polynovo has a strong future as evidenced by its ability to secure a wide range of development agreements with some of the world's major medical device companies," Metabolic said.

"Further to our announcement on March 4, 2009 we advise that Polynovo continues to receive ongoing interest from new licencees in relation to its Novosorb technology," the company said.

Metabolic said the Polynovo board would undertake an ownership and funding review "to determine the likely funding requirements of the business and the optimal ownership structure" which would be reported to shareholders by July 31, 2009.

Metabolic fell 0.8 cents or 18.2 percent to 3.6 cents.

STIRLING PRODUCTS

Stirling Products has added AIDS to the indications that can be assisted by its “natural botanical immuno-modulator” Immunoxel.

Stirling has previously said Immunoxel was 100 percent effective in treating resistant tuberculosis (BD: Apr 16, 2009) and had efficacy against the H1N1 influenza or “swine flu” Apr 29, 2009).

Stirling said results of a clinical trial of Immunoxel in AIDS patients had been published inan article entitled ‘Effect of immunomodulating adjuvant Dzherelo [Immunoxel] in HIV infected patients receiving standard antiretroviral therapy’ in the May 2009 issue of ‘The Open Virology Journal’ available at http://www.bentham-open.org.

Stirling said immunotherapeutic options for AIDS patients were “practically non-existent and largely unsuccessful”.

The company said Ukrainian doctors led by the head of the Kharkov Regional AIDS Center Prof Lyudmila Nikolaeva using Immunoxel in a clinical trial, developed “a highly successful method of enhancing the outcome of antiviral therapy, which at the same time helps to restore normal immunity”.

Immunoxel was evaluated in an expanded, matched-case comparative clinical trial involving HIV infected patients in the advanced disease stage.

The control group of 20 AIDS patients received standard anti-retroviral therapy while the immune intervention group of 20 HIV patients received 50 drops of Immunoxel twice per day in addition to the standard anti-retroviral therapy.

Stirling said that the total CD3 T-lymphocytes increased slightly in the control group recipients (P=0.06), whereas among those who received Immunoxel they rose significantly (P=0.03).

The population of CD4 T-cells had expanded by a half in the control group (P=0.002), whereas in Immunoxel treated patients they almost doubled (from 184 to 356; P=0.004).

The accrual in absolute and relative number of CD8+ lymphocytes in the control and Immunoxel recipients was not significant.

Stirling managing director Peter Boonen said Immunoxel was “not a drug but a patented natural botanical immunomodulator which has been shown in all trials conducted and published to date to regulate or normalize the immune system far more effectively and powerfully than other products”.

Stirling fell 0.1 cent or 4.35 percent to 2.2 cents.

ARANA

Cephalon International Holdings increased its substantial shareholding in Arana from 89,463,066 shares (39.30%) to 94,790,080 shares (41.64%).

The change was through an increase in takeover acceptances (BD: Feb 27, Mar 2, May 14, 2009).

Arana was up half a cent or 0.37 percent to $1.35.