Biotech Daily

Tuesday February 7, 2012

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: ALCHEMIA UP 17%, NEUREN DOWN 7%**

*** BENITEC, MEDISTEM ddRNAi-STEM CELLS TREATS ARTHRITIS IN MICE**

*** COCHLEAR SURVIVES IMPLANT RECALL WITH RECORD H1 REVENUE**

*** PROBIOMICS EGM BACKS HUNTER TAKEOVER, NAME CHANGE**

*** CLINUVEL FILES SCENESSE EUROPEAN APPLICATION**

MARKET REPORT

The Australian stock market fell 0.51 percent on Tuesday February 7, 2012 with the S&P ASX 200 down 21.8 points to 4274.2 points.

Eleven of the Biotech Daily Top 40 stocks were up, 11 fell, 12 traded unchanged and six were untraded.

Alchemia was the best on yesterday's sales news, up six cents or 17.1 percent to 41 cents with 3.1 million shares traded, followed by Living Cell up 10.4 percent to 5.3 cents with 242,559 shares traded.

Bionomics climbed 9.5 percent; Cochlear was up 7.6 percent; Psivida rose six percent; Benitec and Tissue Therapies were up more than five percent; Prima and Genetic Technologies were up more than three percent; Prana rose 2.9 percent; Biota was up 1.2 percent; with Starpharma up 0.4 percent.

Neuren led the falls, down 0.2 cents or 7.1 percent to 2.6 cents, with 5.2 million shares traded, followed by Bioniche down seven percent to 66 cents with 32,000 shares traded.

Compumedics lost five percent; Allied Health fell 3.3 percent; Acrux, Phosphagenics, Reva and Sirtex shed more than two percent; Clinuvel, Nanosonics and Resmed were down more than one percent; with CSL and QRX down by less than one percent.

BENITEC BIOPHARMA

Benitec says that with the San Diego, California-based Medistem it has treated rheumatoid arthritis in mice using its gene silencing technology applied to stem cell-derived immune system dendritic cells.

Benitec said the studies were led by the University of Western Ontario Dr Wei-Ping Min with Benitec chief executive officer Dr Peter French and Medistem scientist Dr Rosalia De Nochea Champion as co-authors on a paper entitled 'Gene silencing of IL-12 in dendritic cells inhibits autoimmune arthritis' published in the Journal of Translational Medicine on January 21, 2012.

An abstract is at http://www.translational-medicine.com/content/10/1/19/abstract.

Dr French said that in 2003, Dr Min's group and Medistem chief executive officer Dr Thomas Ichim, "were the first to apply the technology of RNA interference to the immune system, by silencing the autoimmune disease-associated gene IL-12p352".

"In the current paper, Dr Min expanded these studies to a disease-relevant model, and using stem cell-derived dendritic cells was capable of developing promising preclinical data relevant to rheumatoid arthritis," Dr French said.

Dr French said that by specifically silencing various genes Benitec's DNA-directed RNA interference (ddRNAi) technology was capable of modulating stem cells outside the body, in order to endow them with new desired therapeutic activities.

Benitec said the first clinical study which combined stem cell therapy with its ddRNAi technology was in a trial of AIDS-related lymphoma patients, with results published in 2010 showing the safety and feasibility of the approach.

Benitec said that ddRNAi was used to generate dendritic cells that acted as a 'tolerogenic vaccine', which specifically blocked the pathological immune response in rheumatoid arthritis, without blocking healthy immune responses.

The company said that it was "contemplated that by blocking pathological immunity, ddRNAi-modified stem cell-based therapies, such as those being developed by Medistem, could provide novel treatment and curative approaches to tissue that has been damaged [and] in the case of rheumatoid arthritis the tissue would be cartilage and synovium".

"Medistem is the first company to take a stem cell from discovery to clinical trials in the short span of four years" said Dr Min.

"This is a unique example of merging basic research, as performed in my laboratory with the translational expertise of Dr Ichim's company," Dr Min said.

Benitec said that Medistem previously published work on rheumatoid arthritis, but the company's main efforts were focused on heart failure, for which it has started a 60-patient double blind, dose-escalating, placebo-controlled trial using its endometrial regenerative cell universal donor stem cell.

"In our opinion the Benitec Biopharma technology platform is the only means of inducing the stable expression of gene silencing in a stem cell," Dr Ichim said.

"Given that Benitec Biopharma has pioneered ddRNAi for human therapy, and has been involved in applying it to stem cell manipulation, we are eager to continue our collaborations and finding means of leveraging the unique properties of the [endometrial regenerative cell] with the transformational technology of ddRNAi to develop novel cell therapies for a range of chronic life-threatening human diseases," Dr Ichim said.

"Benitec Biopharma and Medistem are in discussions as to how to advance this work both in rheumatoid arthritis and in a range of other disease states that would lend themselves to such a novel combination therapy," Dr French said.

Benitec was up 0.1 cents or 5.3 percent to two cents with 51.3 million shares traded.

COCHLEAR

Cochlear chief executive officer Dr Chris Roberts says the agility of the company's supply chain allowed it to cope with the CI-500 recall and increase total implants and revenue in the six months to December 31, 2011.

Cochlear recalled its Nucleus C-500 implant last year and later attributed the cause of the failure to the brazing process during manufacturing (BD: Sep 12, Dec 20, 2011).

Today, Cochlear announced a record first half-year revenue of $387.5 million, up three percent on the previous corresponding period, but the recall costs gave the company its first half year net loss after tax since listing on the ASX of $20.4 million.

Cochlear said that total recall costs were $138.8 million.

Dr Roberts told a teleconference that 2.4 percent of the 30,000 units implanted had failed and would require replacing.

Dr Roberts said some patients had both ears implanted while others received a single implant, implying that fewer than 720 patients required implant replacement.

Dr Roberts said that "several thousand" but fewer than 5,000 implants had been recalled from clinics.

In explaining how Cochlear handled the product recall, Dr Roberts said the company "faced the brutal reality of the situation and acted decisively [and was] guided by what was best for the recipients".

He said being able to replace the CI-500 with the earlier model 24RE was "a reflection of the confidence in the flexibility and agility of manufacturing, back office and global supply chain of getting inventory to surgeries".

"When the recall occurred it was probably at the time the company was in its strongest position," Dr Roberts said. "I am very proud of team Cochlear."

In its half year results, Cochlear said that unit sales were down nine percent to 10,724 which did not include more than "2,300 implant units shipped post recall and not recognized as revenue", but sales were up five percent "in constant currency".

Cochlear said that a final 60 percent franked dividend of $1.20 a share would be paid up 14 percent on the six months to December 31, 2010.

Cochlear said implant sales revenue was up one percent to $311.5 million, bone-anchored hearing aid sales were down 13 percent to 39.7 million and the foreign exchange gains was up 66 percent to $36.3 million in the six months to December 31, 2011.

Dr Roberts said the CI-24RE was "the most reliable implant on the market" and the CI-500 would return once the issues had been resolved and following regulatory and reimbursement re-approval.

Dr Roberts was unable to give the teleconference a time-frame for the return.

"We don't believe we have lost market share, despite the return to the market of a competitor," Dr Roberts said.

Cochlear was up $4.41 or 7.6 percent to $62.52 with 723,016 shares traded.

PROBIOMICS, HUNTER IMMUNOLOGY

The ASX says that Probiomics securities have been suspended, following shareholder approval of resolutions on the takeover by Hunter Immunology (BD: Oct 11, 2011).

Probiomics shareholders approved the reverse takeover overwhelmingly with the closest vote, on a $200,000 capital raising at 0.6 cents a share, approved by 47,671,607 proxy votes in favor with 743,666 proxy votes against.

Shareholders elected directors Jeremy Curnock Cook, David Radford, Doug Wilson, William Harrison, Glenn Crisp, Ian Mutton and approved the change of name to Bioxyne.

Probiomics last traded at one cent.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has submitted its marketing authorisation application for afamelanotide 16mg implant (Scenesse) to the European Medicines Agency.

Clinuvel said that the application covered the use of Scenesse as a prophylactic in adult patients with erythropoietic protoporphyria (EPP), which caused intolerance to light.

The company said the application for Scenesse, which received orphan drug designation for EPP in 2008, would be reviewed under the EMA's centralized procedure, allowing the marketing of Scenesse in 27 European Union member states as well as Norway, Iceland and Liechtenstein.

Clinuvel chief scientific officer Dr Hank Agersborg said the company was "confident that we have provided sufficient data to demonstrate that Scenesse is a safe and clinically meaningful treatment for EPP".

"We firmly believe that our application will withstand the rigor of the regulatory review," Dr Hank Agersborg said.

Clinuvel chief executive officer Dr Philippe Wolgen said the filing was "an important milestone [and] another landmark among the innovative therapies developed by the biotech sector, as afamelanotide is the first ever melanocortin filed for marketing approval".

Clinuvel said that erythropoietic protoporphyria was a rare genetic disease found mainly in fair-skinned people and was characterized by severe phototoxicity or light intolerance of the skin resulting in intolerable pain, swelling and scarring, usually of exposed areas such as the face, hands and feet.

The company said that symptoms varied from mild to extreme pain requiring hospitalization and patients often lead an indoors and sheltered life, avoiding light and ultra-violet exposure to prevent symptoms.

Clinuvel said there was no known effective treatment for EPP, which affected about 10,000 people globally, with an estimated 4,000 patients in Europe.

Clinuvel fell three cents or 1.35 percent to $2.20.