



Biotech Daily

Monday March 5, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: CELLMID UP 8%, ANTEO DOWN 8%**
- * **LA TROBE UNI, ADALTA, ROCHE COLLABORATE ON SHARK ANTIBODIES**
- * **PHOSPHAGENICS, NIPPON ZOKI 'PRE-LICENCE' FOR TPM-DICLOFENAC**
- * **LEUKAUMIA FOUNDATION \$585k FOR WEHI**
- * **CELERA-QUESTS USING CELLMID MIDKINE IN LUNG CANCER TEST**
- * **BENITEC LICENCES ddRANi FOR HIV TO CALIMMUNE**
- * **ALLIED PREPARES GLOBAL ADAPT REGULATORY APPLICATIONS**
- * **IMMURON CEO JOE BAINI NO LONGER INTERIM**
- * **CYCLOPHARM LOSES DIRECTOR JOHN SHARMAN**

MARKET REPORT

The Australian stock market fell 0.24 percent on Monday March 5, 2012 with the S&P ASX 200 down 10.1 points to 4263.0 points.

Fourteen of the Biotech Daily Top 40 stocks were up, nine fell, 10 traded unchanged and seven were untraded. All three Big Caps were up.

Cellmid was the best, up 0.1 cents or 8.3 percent to 1.3 cents with 4.2 million shares traded, followed by Phylogica up 7.3 percent to 4.4 cents with 4.4 million shares traded.

Allied Health and Benitec climbed more than five percent; Antisense was up 4.8 percent; Bionomics and QRX were up more than three percent; Avita, Ellex and Resmed rose more than two percent; Acrux, Mesoblast and Tissue Therapies were up more than one percent; with Cochlear, CSL, Reva and Universal Biosensors up by less than one percent.

Anteo led the falls, down 0.7 cents or 8.4 percent to 7.6 cents, with 7.3 million shares traded.

Clinuvel lost 6.2 percent; Living Cell fell 5.15 percent; Genetic Technologies was down 4.8 percent; Nanosonics, Sirtex and Sunshine Heart shed two percent or more; with Heartware and Impedimed down one percent or more.

LA TROBE UNIVERSITY, AD ALTA, ROCHE

La Trobe University says that a collaboration with Roche on shark antibodies holds the potential for new drugs and diagnostic agents.

A La Trobe media release said that the work was based on research led by its Institute of Molecular Science Prof Michael Foley, building on discoveries that shark antibodies could offer advantages over existing therapies for cancers and autoimmune diseases.

The media release said the agreement between Roche and Melbourne-based Adalta, founded by Prof Foley, aimed to identify and evaluate the way in which small antibodies isolated from shark blood were able to bind to a diagnostic target.

The media release said that Prof Foley and his co-researchers had built the first test tube library of disease-targeting antibodies based on modified shark antibodies.

Prof Foley said that shark antibodies were very small and extremely stable protein molecules, particularly good at seeking out and binding to target cells.

"Because they are extremely stable, they may overcome some of the problems encountered with traditional human antibodies when stored and used at high temperatures," Prof Foley said. "Because of their small size and stability, such new therapies can be manufactured in bacterial systems rather than in animal cells, as is ... the case for therapeutic antibodies and it raises the possibility that they may be taken orally instead of injected. So the next generation of pharmaceuticals might make good use of these small proteins, and sharks have them naturally in their blood."

Prof Foley said Adalta would screen his shark antibody library and provide relevant shark antibody binders to Roche for further evaluation.

He said the research involved taking genes from sharks and modifying them in the laboratory by inserting random sequences, mimicking the way the human immune system worked, to develop antibodies capable of a defensive response.

Prof Foley said that shark antibodies had a finger-like loop that could bind into a cavity on a target protein.

"When we saw pictures of the shark antibody binding to a hole in the protein, we immediately thought of a situation like the flu," Prof Foley said. "That's because this sub-cellular sabotage was similar to that involved in the development of the anti-influenza pharmaceutical, Relenza."

"It's like covering up part of a keyhole," Prof Foley said. "You don't have to cover the whole keyhole; if you cover up part of it, you can't get the key in."

Adalta is a private company.

PHOSPHAGENICS

Phosphagenics says it has "a pre-licensing agreement" with Japan's Nippon Zoki Pharmaceutical Co.

Phosphagenics said a material transfer agreement enabled Nippon Zoki to test and assess its tocopheryl phosphate mixture or TPM diclofenac topical non-steroidal pain formulation for its suitability as a prescription item in the US and Japan markets.

The company said that if tests were successful, the parties intended to enter into licensing arrangements.

Phosphagenics said the agreement was the second arrangement negotiated for TPM-diclofenac (Voltaren) following the agreement with Themis Medicare for the Indian market (BD: Nov 2, 2011).

The company said it was in discussions with a company for the balance of the global over-the-counter diclofenac market, worth more than \$US1 billion a year.

Phosphagenics was unchanged at 21 cents with nine million shares traded.

WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute has received \$585,000 in Leukaemia Foundation funding to investigate new treatments for chemotherapy-resistant blood cancers.

The Institute said that blood cancers, including leukaemias, lymphomas and myelomas, made up about 10 percent of all cancers diagnosed each year in Australia.

WEHI said that Dr Kylie Mason was awarded \$100,000 to study the role of a pro-survival protein implicated in some blood cancers resistant to chemotherapy.

WEHI said that the Mcl-1 protein was important in the programmed cell death process, but was overproduced in some cancers, causing the cells to become unresponsive to stimuli that instruct them to die, such as DNA damage caused by chemotherapy.

Dr Mason said the funding would help her explore whether Mcl-1 could be a useful drug target for treating some chemotherapy-resistant leukaemias, lymphomas and multiple myelomas.

WEHI said that research by Dr Marco Herold on the role of another Bcl-2-related protein would be supported by \$100,000 in funding to study the role of the cell-survival protein A1/Bfl1 in the development of blood cancers.

"High levels of A1/Bfl1 has been reported in several types of leukaemias and lymphomas, and has been implicated as a cause of chemotherapy resistance in chronic lymphocytic leukaemias, lymphomas and other cancer cells," Dr Herold said.

The Institute said Dr Matt McCormack would receive \$100,000 to develop new treatments for the common childhood cancer, T-cell acute lymphocytic leukaemia (T-ALL).

The Institute said that Matt Witkowski and Sophie Lee were awarded Ph D scholarships for their studies into blood cancer.

CELLMID

Cellmid says Celera-Quest Diagnostics second annual report for its lung cancer diagnostic licence, confirmed that midkine is one of its six biomarkers.

Cellmid said that a Celera-Quest Diagnostics study showed that the six marker lung cancer panel showed 94 percent specificity and 70 percent sensitivity in accurately classifying non-malignant nodules identified during computed tomography scanning of a high risk smoker population.

The company said that although the rate of smoking was declining there were an estimated 94 million current and past smokers in the US at risk of contracting lung cancer.

Cellmid said that mortality caused by lung cancer could be markedly reduced if cancerous nodules were detected and removed very early, but it was usually the case that once patients were symptomatic, the cancer had already spread from its initial site, thereby reducing the chances of successful treatment.

The company said that population screening of at-risk groups had been proposed as one way to reduce lung cancer mortality and a US National Institute of Health large-scale study of 53,454 current and ex-smokers aged 55 to 74 years, found that screening by computed tomography scanning reduced mortality by 20 percent in six years.

The company said that the low specificity of computed tomography (CT) scanning was a concern as the same study showed that 25 percent of the solitary nodules identified by CT scan proved to be non-cancerous after lung biopsy (75% specificity).

Cellmid said that unnecessary biopsy of otherwise benign nodules created additional costs and significant morbidity for an already large patient group.

The company said that Celera-Quest Diagnostics' six marker lung cancer panel with its 94 percent specificity could become a useful adjunct to imaging.

Cellmid was up 0.1 cents or 8.3 percent to 1.3 cents with 4.2 million shares traded.

BENITEC BIOPHARMA

Benitec says it has licenced its DNA-directed RNA interference (ddRNAi) technology to the US based Calimmune for use in the field of HIV/AIDS.

Benitec said the non-exclusive agreement covered the world-wide application of ddRNAi to target up to three key viral and cellular genes identified as significant therapeutic targets to inhibit HIV/AIDS infection.

Benitec said that while the terms were in confidence, they were “within expected guidelines for biotech companies in the early stage of development”.

The company said that Calimmune’s approach to the application of ddRNAi to HIV/AIDS had been developed with core technology from the lab of Dr David Baltimore, a Nobel Laureate in the area of HIV/AIDS.

Benitec said it expected Calimmune’s “proactive and innovative approach will lead to a clinical trial within the next 12 months”.

The company said that Calimmune’s Sydney-based chief scientific officer Dr Geoff Symonds would join the Benitec chief investigators group, a team that included RNAi and HIV expert, California’s City of Hope Prof John Rossi.

Calimmune is believed to be based in Tucson, Arizona.

Benitec said the licence was in line with its previously announced strategy to seek long-term partners in the development of ddRNAi-based anti-HIV therapeutics, motivated by the success of the City of Hope Hospital clinical trial (BD: Feb 9, 2009).

Benitec chief executive officer Dr Peter French said the Calimmune was “the first of many such licencing agreements with [biotechnology] and biopharmaceutical companies who see the potential of ddRNAi to transform medical treatment in a range of diseases”.

Benitec was up 0.1 cents or 5.6 percent to 1.9 cents with 4.6 million shares traded.

ALLIED HEALTHCARE GROUP

Allied Health says it has filed its regulatory application to the Australian Therapeutic Goods Administration and is preparing applications for Europe and the US.

Allied’s tissue engineering and regenerative medicine division Celxcel chief executive officer Bob Atwill told Biotech Daily that the TGA filing for the Adapt technology, which underpins its bovine cardiac patch, was completed in January 2012 and the company was finalizing further questions with the Australian regulatory body.

The Adapt process removes all cells, RNA and DNA, effectively leaving a clean collagen scaffolding and can be used to create kangaroo patches which are thinner and stronger than bovine tissue (BD: Feb 19, 2009).

Mr Atwill said that Allied Health expected TGA approval by the end of 2012.

Allied said that it had begun discussions with SGS to act as its notified body for Conformité Européenne (CE) mark and the group would be able to assist in obtaining Canadian marketing authorization, in addition to Taiwan and Hong Kong approval.

The company said it was planning its US Food and Drug Administration application and was investigating the best approach for a US submission.

Mr Atwill said the Adapt-treated patch had been successfully tested “in a number of in-vitro, in-vivo models and a phase II clinical trial setting to assess the durability, biocompatibility and calcification potential of the implant”.

Allied said that in addition to cardiovascular products, it was also evaluating how the process could be used in pelvic floor reconstructions, hernia repair, orthopaedics and as a biological scaffold to grow and deliver stem cells.

Allied Health was up 0.2 cents or 5.7 percent to 3.7 cents with 1.9 million shares traded.

IMMURON

Immuron says that interim chief executive officer Joe Bains has been formally appointed as chief executive officer.

Immuron said Mr Bains was appointed interim chief executive officer in 2011 and had been “instrumental in transforming the company over the last 12 months” (BD: Jan 17, 2011).

Immuron fell 0.2 cents or 6.25 percent to three cents.

CYCLOPHARM

Cyclopharm says that John Sharman resigned as a non-executive director on February 29, 2012.

Cyclopharm said that Mr Sharman “was unable to dedicate sufficient time to the role due to pre-existing executive commitments”.

Mr Sharman is the chief executive officer of Medical Developments International.

Cyclopharm was untraded at 3.6 cents.