



Biotech Daily

Wednesday May 7, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: BENITEC UP 9%, PRANA DOWN 11%**
- * **ADMEDUS FIRST US CARDIOCEL TISSUE SALE**
- * **CSIRO, DEAKIN UNI NEW BIO-SECURE ANTI-VIRAL FACILITY**
- * **CELLMID PREPARES CAB102 FOR HUMAN CANCER TRIALS**
- * **ANALYTICA EXPECTS US, AUSTRALIAN PERICOACH REIMBURSEMENT**
- * **NOMINATIONS OPEN FOR \$80k GSK RESEARCH EXCELLENCE AWARD**
- * **NUSEP REQUESTS CAPITAL RAISING TRADING HALT**
- * **UNIVERSITY OF QUEENSLAND HOSTS JULY NANO-BIO CONFERENCE**

MARKET REPORT

The Australian stock market fell 0.83 percent on Wednesday May 7, 2014 with the S&P ASX 200 down 45.6 points to 5,435.8 points.

Seven of the Biotech Daily Top 40 stocks were up, 21 fell, nine traded unchanged and three were untraded. All three Big Caps fell.

Benitec was the best, up 8.5 cents or 9.4 percent to 98.5 cents with 884,279 shares traded.

Cellmid climbed four percent; Analytica, Uscom and Viralytics were up more than three percent; Pharmaxis rose 2.8 percent; with Nanosonics up 0.6 percent.

Prana led the falls, down two cents or 11.1 percent to 16 cents with 1.3 million shares traded.

Osprey lost 7.55 percent; Bionomics and Clinuvel fell more than six percent; GI Dynamics, Impedimed and Psivida were down five percent or more; Acrux and Living Cell fell four percent or more; Atcor and IDT were down more than three percent; Alchemia, Anteo, Mesoblast and Neuren shed more than two percent; Cochlear, Oncosil, Phosphagenics, Resmed, Tissue Therapies and Universal Biosensors were down more than one percent; with CSL, Sirtex and Starpharma down by less than one percent.

ADMEDUS

Admedus says the first US sale of its Cardiocel bovine tissue is to “a major heart surgery hospital on the US East Coast”.

Admedus said the first order, following the February US Food and Drug Administration clearance, was two months ahead of internal timelines (BD: Feb 14, 2014).

The company said the focus for the sales team would be to have Cardiocel used in key centres across Europe and the US.

Admedus chief executive officer Lee Rodne said the sale was “an important milestone for the company as we look to grow our revenue over the coming 12 months and beyond”.

“We are aiming for Cardiocel to be in use in 15 key centres in Europe and the US over the next 12 months, which will provide us with a significant presence in the market,” Mr Rodne said.

The company said that it presented Cardiocel to US cardio-thoracic surgeons during the American Association of Thoracic Surgeons conference in Toronto and the sales team was working with US based cardio-thoracic surgeons, communicating the benefits of Cardiocel and its advantages over existing products on the market.

Admedus said that in Europe it officially launched Cardiocel late in 2013, with the aim of introducing it into 15 key cardio-thoracic centres and to date, Cardiocel had been used in eight of the target centres, with several more expected to come on-stream by mid-year.

The company said that surgeons who had used Cardiocel in surgical procedures had not reported any issues.

Admedus said it was seeking approval in a number of other jurisdictions to meet its global launch plans and Cardiocel was used in Australia under the Authorised Prescriber Scheme with more than 100 patients implanted.

Admedus was unchanged at 12.5 cents with 4.3 million shares traded.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says that with Deakin University it has opened a new immunology research facility to improve the ability to develop treatments for highly infectious viruses.

The CSIRO said that the bio-secure unit would be built at the Australian Animal Health Laboratory in Geelong.

Laboratory director Dr Kurt Zuelke said the new facility would provide more specialized techniques to help pin-point the immune mechanisms employed by various animal hosts.

Dr Zuelke said the facility would be “critical in helping us develop new, more natural, therapeutics and boost our work in preventing, detecting and treating emerging infectious diseases”.

“Researchers in Geelong are already world renowned for their work with zoonotic agents, those that can pass from animals to people, but we can now compare the immune responses of different animal species, including humans, to the most pathogenic infectious agents,” Dr Zuelke said.

The CSIRO said that by understanding how pathogens affected different hosts, for example, how pigs or poultry protect themselves from influenza, researchers hoped to harness a host's successful immune mechanism to develop new therapeutic approaches to manage the viruses.

Dr Zuelke said he was in discussions with researchers from the UK and US who were “keen to have access to this facility to further their research into diseases of pigs”.

The CSIRO said that access to a comparative immunology laboratory would enable research scientists to work on infected live cells, all contained within the quarantined bio-secure area of one of the world's most sophisticated high-containment laboratories.

CELLMID

Cellmid says it has completed humanization, testing and selection of its lead anti-midkine antibody CAB102 for its planned first-in-class clinical trials in oncology.

Cellmid said that CAB102 had been shown to significantly reduce chemotherapy resistance in a preclinical model of lung cancer in combination with carboplatin.

Cellmid chief executive officer Maria Halasz told Biotech Daily that the company expected to take CAB102 into human clinical trials in 2015, "most likely for lung cancer".

The company said that in addition to functional activity in-vivo, CAB102 produced strong in-vitro functionality in specifically designed midkine migration assays.

Cellmid said that initial cell expression and stability data confirmed that it could be manufactured commercially, making it a feasible drug product.

Ms Halasz said that "with the completion of lead selection and after a well-planned and extensive testing program, our preparations for clinical trials are well on track".

The company said that selection of CAB102 was the result of a pre-clinical program in which dozens of its proprietary and patent-protected murine anti-midkine antibodies were assessed for efficacy and mechanism of action both in-vivo and in-vitro.

Cellmid said that the two most promising murine antibodies identified were humanized by the Hertfordshire UK-based Biotechnol and of the 78 humanized antibody variants generated by Biotechnol the six most promising candidates were then assessed further for mechanism of action, in-vivo anti-tumor efficacy and manufacturability including cell-line expression, antibody purification, molecular stability and absence of aggregates.

The company said that all six candidates demonstrated similar or improved affinity when compared to their murine precursors and specificity for midkine was retained, with no evidence of binding to other proteins.

Cellmid said that a preliminary assessment showed all six candidates were secreted at commercially viable concentrations during cell culture, all six candidates were readily purified and had been confirmed as structurally stable and aggregate free.

The company said that the six candidates were then tested for functional activity using an in-vitro cell migration inhibition assay and an in-vivo tumor xenograft model in combination with carboplatin, the standard chemotherapy in lung cancer.

Cellmid said that the cancer xenograft studies were performed in the widely-studied K-Ras mutant, highly refractory and difficult to treat human non-small cell lung carcinoma cell-line NCI-H460.

The company said that as expected, and consistent with clinical experience, carboplatin did not significantly reduce tumor volume or mass when used alone compared to untreated controls in the NCI-H460 model.

But three of the six humanized antibody candidates significantly reduced tumor growth when combined with carboplatin, Cellmid said.

The company said that when combined with carboplatin, CAB102 demonstrated the greatest efficacy, with mean tumor volumes at 21 days post treatment reduced by 50 percent with $p < 0.001$ compared to untreated control and $p < 0.01$ when compared to the carboplatin-only treated group.

Cellmid head of product development Darren Jones said that "strong preclinical performance by reducing chemotherapy resistance is important to progress our first-in-class anti-midkine antibody program to the clinic".

"The results are consistent with the independent findings by other research groups confirming [midkine's] role in chemotherapy resistance in glioblastoma and provide a strong commercial rationale for our product development program in multiple cancer types," Mr Jones said.

Cellmid was up 0.1 cents or four percent to 2.6 percent with 13.4 million shares traded.

ANALYTICA

Analytica says its Pericoach intra-vaginal training tool for incontinence will be eligible for both US and Australian reimbursement.

Analytica said that it commissioned an unnamed independent US reimbursement report that verified that US health fund reimbursement would be available for all US patients using the Pericoach for treatment of urinary incontinence when treated by a clinician.

The company said that the report gave "very positive support for the Pericoach system, and validates Analytica's clinician-centric strategy for this market".

Analytica said that the independent review confirmed its own investigations that US Medicare would reimburse the costs of visits to a clinician for patients using the Pericoach. The company said that the Australian Government also recognized urinary incontinence as a chronic condition impacting on quality of life and supported treatment initiatives.

Analytica said that Australia's Medicare reimbursed treatment for stress urinary incontinence by clinicians and physiotherapists.

The company said that reimbursement addressed a cost concern identified by its market research that might have discouraged some patients from seeking professional help.

Analytica chief executive officer Geoff Daly said that "the combination of reimbursement for clinical consultations and the unique advantages of the Pericoach system delivers outstanding value for patients".

"Sufferers of stress urinary incontinence will soon have a very low cost, non-traumatic treatment alternative that actually helps fix their problem with the support from expert clinicians," Mr Daly said.

Analytica was up 0.1 cents or 3.3 percent to 3.1 cents with 12.7 million shares traded.

GLAXOSMITHKLINE

Glaxosmithkline says nominations have opened for its \$80,000 Award for Research Excellence.

Glaxosmithkline said that the Award was in its 34th year and recognized outstanding achievements in medical research.

Glaxosmithkline medical director Dr Andrew Yeates said that the Award was consistent with the company's "commitment to being a research-based company focussed on innovation".

"The work that GSK undertakes, our products and programs are the result of excellence and collaborations in medical research," Dr Yeates said. "As such, we acknowledge the commitment and resources needed in order to achieve innovations in the research arena."

"GSK looks forward to the positive outcomes generated from the research through the assistance from the Award," Dr Yeates said.

Glaxosmithkline said that the winner would be announced on November 5, 2014 at the Annual Research Australia Awards night in Sydney.

Nominations close on June 30, 2014.

More information is at: <http://www.gsk.com.au/research-development.aspx> under 'Awards & Grants'. Email enquires to are.arenominations@gsk.com.

NUSEP

Nusep has requested a trading halt "pending the release of a company announcement in relation to the finalization of a funding agreement".

Trading will resume on May 9, 2014 or on an earlier announcement.

Nusep last traded at 8.5 cents.

UNIVERSITY OF QUEENSLAND

The University of Queensland is hosting the 2014 Nano-Bio Conference in Queensland July 6 to 10, 2014

A University of Queensland media release said that it expected 500 delegates, six international plenary speakers and 65 keynote speakers to attend the Nano-Bio conference, focusing on research at the intersection of biology with nano-science and nanotechnology.

The media release said that the conference would incorporate the International Nano-Bio Conference and the International Conference on Bio-Nano Innovation.

The University said that Seattle, Washington biologist Dr Leroy Hood, the inventor of automated DNA sequencing, Harvard biochemistry Prof Pamela Silver and UK Prof Molly Stevens would be among the plenary speakers.

The University said that the conference would be co-chaired by Australian Institute for Bioengineering and Nanotechnology deputy director Prof Matt Trau and the Commonwealth Scientific and Industrial Research Organisation's biomedical and materials theme leader Dr Keith McLean.

Prof Trau said the conference would have an array of multi-disciplinary science designed to connect world-leading scientists, engineers and entrepreneurs working in biology, nano-science and nanotechnology.

The University said that the estimated 500 participants were aiming to make improvements in areas as diverse as molecular and cellular sensing, stem cells and regenerative medicine , synthetic biology, nano-scaled drug and vaccine delivery, advanced nano-materials for imaging, energy storage and the environment , nano-toxicology and theoretical and computational chemistry.

"The intersection of biology and nano-science represents one of the most exciting wellsprings of scientific innovation and is also a major stimulus for a plethora of high value technologies and industries," Prof Trau said.

The University said that the conference would feature an early career symposium, poster sessions and an industries of the future symposium.

The conference will be held at the University of Queensland's Advanced Engineering Building 49, from July 6 to 10, 2014.

For more information go to: www.2014nanobioaustralia.org.