Biotech Daily

Tuesday June 5, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 14%, IMPEDIMED DOWN 6%**

*** NOVOGEN, MARSHALL EDWARDS ME-143 'LOW TOXICITY'**

*** PRIMA TO LIST ON FRANKFURT EXCHANGE**

*** ALLIED CE MARK APPLICATION FOR CARDIOCEL PATCH**

*** PHOSPHAGENICS: 3M ADHESIVE CAUSED CRYSTALLIZATION**

*** GERMAN RESEARCH BACKS USCOM FOR VENTILATION**

*** HARDING LOEVNER TAKES 5% OF COCHLEAR**

*** CIRCADIAN REQUESTS CAPITAL RAISING TRADING HALT**

*** NUSEP APPOINTS BIOEXPRESS US GEL DISTRIBUTOR**

*** ATCOR WELCOMES HALMA TAKEOVER OF PARTNER SUNTECH**

*** CHALLENGER, NOVAPORT REDUCE 1% IN MEDICAL DEVELOPMENTS**

*** UK'S COLLEGE HILL OPENS MELBOURNE OFFICE**

MARKET REPORT

The Australian stock market climbed 1.47 percent on Tuesday June 5, 2012 with the S&P ASX 200 up 58.7 points to 4043.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, eight fell, 10 traded unchanged and six were untraded. All three Big Caps were up.

Avita was the best, up 2.5 cents or 14.3 percent to 20 cents with 128,252 shares traded followed by Prima up 13.8 percent to 16.5 cents with 5.9 million shares traded and Patrys up 13.6 percent to 2.5 cents with 135,000 shares traded.
Genetic Technologies climbed 7.1 percent, Phosphagenics was up 6.45 percent; Allied Health was up five percent; Pharmaxis and Psivida were up more than four percent; Mesoblast and Reva were up more than three percent; Cochlear rose 2.4 percent; Bioniche, CSL, Sirtex, Tissue Therapies, Universal Biosensors and Viralytics were up more than one percent; with Acrux and Resmed up by less than one percent.

Impedimed led the falls, down two cents or 6.25 percent to 30 cents with 83,666 shares traded. Antisense, Bionomics and Prima lost more than five percent; QRX shed 2.2 percent; with Clinuvel, Heartware and Starpharma down by less than one percent.

NOVOGEN

Novogen's 63.5 percent subsidiary Marshall Edwards says that in a phase I trial ME-143 was generally well tolerated with minimal toxicity in patients with solid refractory tumors.
Novogen said the data was presented at the American Society of Clinical OncologyAnnual meeting in Chicago by a co-investigator, the University of Oklahoma Health Sciences Center's Dr Carla Kurkjian.
"ME-143 appears to be generally well tolerated with minimal toxicity as a single agent in heavily treated patients," Dr Kurkjian said.
"We look forward to further studies of ME-143 in combination with cytotoxic therapies," Dr Kurkjian said.
Novogen said the poster presentation, entitled 'ME-143, a novel inhibitor of tumour-specific NADH oxidase (tNOX): Results from a first-in-human phase I study' was available at www.marshalledwardsinc.com.
Novogen said the open label phase I trial of intravenous ME-143 trial began in September, 2011 following approval of an investigational new drug application by the US Food and Drug Administration and was designed to evaluate the safety and tolerability of ME-143, the company's next-generation nicotinamide adenine dinucleotide (NADH) oxidase inhibitor, in patients with refractory solid tumors and characterize its pharmacokinetic profile.
The company said that 15 patients were enrolled in escalating dose cohorts of 2.5mg/kg, 5mg/kg, 10mg/kg and 20mg/kg.
The company said that stable disease was observed in one patient at more than 15 weeks, which was comparable to phase I studies of phenoxodiol, the company's first-generation NADH oxidase inhibitor, in which stable disease was also the best response observed.ME-143 was generally well tolerated at all dose levels on a weekly dosing schedule and the maximum tolerated dose was defined as 20 mg/kg.
Marshall Edwards chief medical officer Dr Robert Mass said the company achieved its main objective in the trial "specifically, to establish a recommended dose for the next phase of development with ME-143".
"With the exception of a serious infusion reaction in one patient at the highest dose level, ME-143 was generally well tolerated," Dr Mass said.
"In addition, the pharmacokinetic profile of intravenous ME-143 resulted in drug levels that were approximately 30 times higher than the exposure achieved in a phase II trial of intravenous Phenoxodiolin combination with platinum-based chemotherapy in women with platinum-resistant ovarian cancer," Dr Mass said.
"These results enable us to better prepare for the first of our phase II efficacy studies of ME-143 in combination with standard-of-care chemotherapy later this year," Dr Mass said.
Novogen fell 0.1 cents or 1.1 percent to nine cents with 10 shares sold.

PRIMA BIOMED

Prima says its American depository receipts (ADRs) will list on the entry standard of the Frankfurt Stock Exchange from today.
Prima said the ADRs have traded under the code PBMD on the Nasaq since April 16, 2012 with each ADR equivalent to 30 Australian shares.
Prima said the Frankfurt listing acknowledged the importance of Germany and Europe with a wholly-owned subsidiary in Leipzig, significant financial support for its phase III study from the Sächsische Aufbaubank, as well as working with the Fraunhofer Institute for Cell Therapy and Immunology for production of its ovarian cancer vaccine CVac.
Prima was up two cents or 13.8 percent to 16.5 cents with 5.9 million shares traded.

ALLIED HEALTHCARE GROUP

Allied Health says it has submitted a Conformité Européenne (CE) mark application for its bovine tissue matrix Cardiocel to its European notified body.

Allied said that, as well as the notified body, the Cardiocel submission would be evaluated by the UK Medicines and Healthcare Regulatory Agency.

Allied managing director Lee Rodne said the filing was “another step towards the commercialization of the Cardiocel and Adapt technology and part of the company strategy to bringing products to market in the regenerative medicine multi-billion dollar markets”.

“The next 12 to 18 months will be exciting for our regenerative medicine franchise as it seeks approval in numerous jurisdictions,” Mr Rodne said.

The company said that the application dossier contained extensive data generated around the Adapt technology and the Cardiocel cardiovascular patch.

Allied executive and Cardiocel chief executive officer Bob Atwill said the CE mark submission was “a key value driver for the Allied Healthcare Group”.

Allied said that the importance of the application was that Europe was one of the major markets for regenerative medicine products and if successful, Cardiocel could provide the potential for significant revenue for the Allied Healthcare Group.

The company said the initial use would be in cardiac surgical repair, such as congenital heart disease, which was one of the major causes of death in infants.

Allied said that the Adapt platform technology had the potential to have a significant impact on the global market for structural heart defect repair, estimated at more than $3 billion, with Europe one of the major markets.

Allied said it expected to file for US marketing approval for Cardiocel later this year.

The company said it was also evaluating how its Adapt platform technology could be used in pelvic floor reconstructions, hernia repairs, orthopaedics and as a biological scaffold to grow and deliver stem cells.

Allied Health was up 0.1 cents or five percent to 2.1 cents with 1.4 million shares traded.

PHOSPHAGENICS

Phosphagenics says that commercial partner 3M’s adhesive caused crystallization in its tocopheryl phosphate mixture or TPM technology oxycodone patch.

Last month, Phosphagenics said it engaged Germany’s Labtec GmbH to assist with its TPM-oxycodone patch “to enhance the commerciality of the patch and eliminate a minor patch crystallization matter that commonly occurs during development that is normally resolved by optimizing the ratio between solvent and adhesive” (BD: May 23, 2012).

Today the company said its researchers had identified and tested several adhesives that produced superior in vitro results to the 3M TPM-oxycodone patch, which used a proprietary 3M adhesive and had developed crystallization.

Phosphagenics said that several of the new patch formulations incorporating these alternative adhesives demonstrated increased oxycodone delivery and solubility, without any crystallization to date. The company said stability testing was, by its nature, ongoing.

Phosphagenics said that as the patches had alternative adhesives to 3M’s proprietary adhesive, Labtec would conduct the research and development program exclusively.

The company said that in all other respects, the arrangement with 3M remained in place and it would continue to work with 3M.

Phosphagenics said it was on-track to begin the pivotal phase III trial by April 2013.

Phosphagenics was up one cent to 6.45 percent to 16.5 cents with 3.85 million shares traded.

USCOM

Uscom says German research further supports its ultra-sonic cardiac output monitor as the standard of care for cardiac monitoring of critical care patients on ventilators.

Uscom said the monitor had applications in paediatrics, emergency and intensive care medicine and anaesthesia, as well as for management of adult and pediatric sepsis, hypertension, heart failure and for the guidance of cardiovascular fluid and drug therapy.

The company said the study, entitled 'Mechanical ventilation with positive end-expiratory pressure in critically ill patients: comparison of CW-Doppler ultrasound cardiac output monitoring (USCOM) and thermodilution (PiCCO)' was published in Acta Cardiol the journal of the Belgian Society of Cardiology and identified the accurate calibration of ventilators as an important clinical application for the Uscom technology and a new and substantial market.

An abstract is at: http://poj.peeters-leuven.be/content.php?url=article&id=2154208.

Uscom said the study was performed on patients with pneumonia and septic shock admitted to the intensive care unit of Ludwig-Maximilians-University Munich, which found the monitor was "an accurate, easy to use, non-invasive device that detected irregularities in heart function and helped guide medical treatment".

Uscom said the study concluded that its monitor "constitutes an important tool for easy, rapid and reliable diagnosis and haemodynamic monitoring of critically ill patients."

Uscom executive chairman Rob Phillips said the study showed that ventilators should be calibrated with his monitor.

"This is more far reaching, practice changing research which at some time will shift the medical monitoring market," Mr Phillips said.

"Our sector dominating evidence has great value, and our focus is now to develop partnerships with established marketing, distribution and sales organizations which can efficiently and with scale deliver the Uscom technology into multiple revenue opportunities rapidly as practice responds to our mounting evidence," Mr Phillips said.

"These partnerships will allow us to deliver modular versions of Uscom into portable ultrasound units, monitoring suites, and now into ventilators, as well as continue with stand alone sales into current and new markets," Mr Phillips said.

"These licensing partnerships are envisaged to deliver strong profitability to shareholders and be the foundation of the Uscom of the future," Mr Phillips said.

Uscom said that the ventilation of patients with impaired lung function was an increasingly common treatment in critical care medicine and inappropriate ventilator settings could impair cardiac function, making the patient worse.

The company said that cardiac monitoring during ventilation was infrequent because the monitoring methods are invasive and/or inaccurate.

Uscom said its monitor was cleared for use by the US Food & Drug Administration and was sold in North America, South America, Europe, the Middle East, Australia, New Zealand, China and South East Asia.

Uscom was untraded at nine cents.

COCHLEAR

The Bridgewater, New Jersey-based Harding Loevner LP has become a substantial shareholder in Cochlear with the acquisition of 2,861,083 shares or 5.03 percent.

The initial substantial shareholder notice said the investment management firm acquired 2,413,437 Australian shares and 895,291 American depository receipts equivalent to 447,646 Australian shares between February 1 and June 1, 2012.

Cochlear was up $1.47 or 2.4 percent to $63.62 with 176,454 shares traded.

CIRCADIAN TECHNOLOGIES

Circadian has requested a trading halt “pending an announcement … in respect of a proposed capital raising”.
Trading will resume on June 7, 2012 or on an earlier announcement.
Circadian last traded at 52 cents.

NUSEP

Nusep says it has appointed the Kaysville Utah-based Bioexpress to distribute its analytic gels in the US.
Nusep said that Bioexpress was a leading distributor of equipment, consumables, reagents and laboratory essentials into the US life science research marketplace and was the preferred supplier to several US academic institutions, opening a number of new markets for Nusep.
The company said its gels complemented Bioexpress’s existing product range enabling Bioexpress to complete its electrophoresis product offering.
Nusep said the agreement would significantly expand its access to the key US market and expected Bioexpress to generate more than $250,000 of gels sales in the first full year.
Nusep managing director Dr Hari Nair said the agreement was “a significant achievement for Nusep as it strengthens our relationship with one of the premier Life Science companies in the US and broadens the reach for our gel products”.
Nusep was unchanged at three cents.

ATCOR MEDICAL

Atcor says the acquisition of strategic alliance partner Suntech Medical by Halma Plc is good for all three companies.
Atcor said Halma would pay an initial cash consideration of GBP29.7 million ($A46.8 million) for Suntech and a contingent consideration of up to GBP3.9 million if earnings for the year to December 2012 exceeded a pre-determined target.
Atcor said that Suntech recorded financial year 2011 sales of GBP14.8 million and an operating profit of GBP3.5 million.
The company said that in July, 2011, it announced a multi-year worldwide clinical trials distribution and data management agreement in which it co-marketed the Suntech Oscar2 ambulatory blood pressure monitor and in January, 2012 the two companies announced a strategic alliance aimed at improving blood pressure measurement and overall cardiovascular health assessment and management.
Atcor chief executive officer Duncan Ross said the acquisition was “very good for our partner Suntech and therefore for Atcor”.
“Suntech is now backed by a large, successful organization that allows its business units to retain, leverage and keep in place their original branding and management process,” Mr Ross said.
Mr Ross said that in the past 10 years Halma spent more than GBP350 million acquiring more than 25 businesses.
Atcor said that Halma was listed on the London Stock Exchange with a market capitalization of about GBP1.5 billion.
The company said that Halma had businesses in 23 countries and major operations in Europe, the USA and Asia.
Atcor was up half a cent or 6.7 percent to eight cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Challenger and Novaport Capital have again reduced their substantial shareholding in Medical Developments from 3,306,103 shares (6.14%) to 2,859,870 shares (5.14%).
The substantial shareholder notices, both from Pitt Street, Sydney said the companies sold the 446,233 shares for $286,315 or an average price of 64.2 cents each.
Last year, Novaport said it acquired 4,769,957 shares for $1,860,283 or 39 cents a share and in February this year sold 400,000 shares for $218,997 or an average price of 54.7 cents each (BD: Jan 31, 2011; Feb 27, 2012).
Novaport is an independent boutique investment group, related to the Challenger group.
Medical Developments was unchanged at 79.5 cents.

COLLEGE HILL

Public relations company College Hill has formally opened its Melbourne office with Dr Douglas Pretsell as senior consultant.
College Hill said that Dr Pretsell moved to Melbourne from England in February this year.
The company said the new office was co-located with the Medical Research Commercialisation Fund and Brandon Capital in Collins Street, Melbourne.
College Hill Life Sciences managing partner Sue Charles said the company began its Australian operations in 2010 and that she was based in Sydney and London.
The company said that Dr Pretsell had more than 15 years' experience in life science communications and was experienced across corporate, financial and product communications.
Dr Pretsell has a Ph D in neuroscience from the University of Cambridge and completed a post-doctoral research fellowship on HIV and dementia at Edinburgh University.