Biotech Daily

Wednesday September 18, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CELLMID UP 12%; NEUREN DOWN 8%**

*** VIRALYTICS CAVATAK MEETS MELANOMA ENDPOINT AHEAD OF PLAN**

*** CALZADA FILES NOVOSORB FDA WOUND DRESSING APPLICATION**

*** USCOM RAISES $1m**

*** OSPREY CINCOR DYE TRIAL CONTINUES, 'AVERT' THE PRIORITY**

*** IMUGENE DISCONTINUES LINGUET IBUPROFEN**

*** BIO-MELBOURNE BREAKFASTS ON EMERGING TECHNOLOGY JOBS**

MARKET REPORT

The Australian stock market fell 0.25 percent on Wednesday September 18, 2013 with the S&P ASX 200 down 13.1 points to 5,238.1 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and five were untraded.

Cellmid was the best, up 0.3 cents or 12.0 percent to 2.8 cents with 690,520 shares traded, followed by Osprey up 10.8 percent to 72 cents with 521,470 shares traded and Viralytics up 10.1 percent to 38 cents with 1.5 million shares traded.

Prana climbed seven percent; Benitec was up 5.3 percent; Alchemia rose four percent; Anteo, Atcor and Clinuvel were up more than three percent; Starpharma rose 2.2 percent; Living Cell was up 1.8 percent; with Acrux, Cochlear and Sirtex up by less than one percent.

Neuren led the falls, down 0.8 cents or 8.0 percent to 9.2 cents with 3.6 million shares traded.

Allied Health and Tissue Therapies lost more than six percent; Medical Developments fell 5.05 percent; Genetic Technologies, GI Dynamics, IDT, Impedimed, Patrys, Prima and Universal Biosensors shed more than two percent; Nanosonics and QRX were down more than one percent; with CSL, Mesoblast, Psivida and Resmed down by less than one percent.

VIRALYTICS

Viralytics says it has achieved the primary endpoint in its 54-patient phase II clinical trial of Cavatak for late stage melanoma patients, prior to completing recruitment.

Viralytics said the phase II trial was a single arm study at 10 US sites and was designed to investigate the safety and efficacy of intra-tumoral Cavatak or Coxsackievirus A21 in 54 evaluable patients with late stage malignant melanoma, known as the 'Calm' study.

The company said that the primary endpoint was immune-related progression-free survival at six months after the first dose of Cavatak.

Viralytics said the primary endpoint was to have 10 patients from a total of 54 evaluable patients reporting immune-related progression-free survival at six months after the first dose of Cavatak, but this was achieved after 30 evaluable patients, representing an immune-related progression-free survival rate so far of 33 percent.

The lead investigator at the Salt Lake City, Utah-based Huntsman Cancer Institute Dr Robert Andtbacka said that "achieving the primary endpoint of the Calm study before patient recruitment has been completed is very encouraging".

"In addition to the positive [immune-related progression-free survival] data we have observed responses in both injected and non-injected lesions," Dr Andtbacker said.

Viralytics chief executive officer Dr Malcolm McColl said the company was "delighted to achieve this major milestone in the development of Cavatak".

"Given the excellent progress achieved to date and the encouraging feedback from key opinion leaders in the melanoma field we also believe it is now timely to consider the design of a randomized study in melanoma patients," Dr McColl said.

Viralytics said other endpoints included durable response rate, one year survival and overall survival, which would be reported as data was generated and analyzed.

The company said that in July the independent data monitoring committee met to review data from the first 35 patients in the study and concluded that Cavatak had met the safety, tolerability and response criteria and the study could progress to full enrolment.

Viralytics said that Cavatak was well-tolerated by patients with no reports of serious adverse events or grade 3-4 adverse events related to the Cavatak treatment.

The company said that there were 44 patients enrolled in the study with full enrolment forecast by the end of 2013.

Viralytics was up 3.5 cents or 10.1 percent to 38 cents with 1.5 million shares traded.

CALZADA

Calzada says wholly-owned subsidiary Polynovo has submitted its 510(k) application to the US Food and Drug Administration for its Novosorb wound dressing.

Calzada said that the wound dressing would be called Novopore in topical negative pressure wound dressings.

The company said that filing the pre-market application followed the pilot clinical trial of Novosorb as a topical negative pressure wound dressing, where it showed safety and efficacy advantages over the market leading treatment, Granufoam (BD: Apr 17, 2013).

Calzada said that the FDA had cited problems with existing topical negative pressure wound products and the pilot trial results indicated that, compared to Granufoam, Novopore reduced dressing fragmentation, reduced risk of infection, reduced the difficulty of dressing removal and reduced undesirable dressing retention in the wound.

The company said that if the 510(k) regulatory submission was successful, Polynovo expected regulatory clearance to market Novopore by April 2014 and was in discussions with potential distribution and marketing partners.

Calzada was up 0.2 cents or 2.7 percent to 7.7 cents.

USCOM

Uscom says it has raised $1,065,000 in a placement to new and current sophisticated investors and the exercise of options by staff at prices between 15 and 20 cents a share.
Uscom said the issue was managed by Lodge Partners and funds would be directed to support sales and marketing initiatives and distribution partnerships.
Uscom was untraded at 18 cents.

OSPREY MEDICAL

Osprey has confirmed that its 600-patient 'Preserv' trial will continue, but the focus will be on the 700-patient 'Avert' trial, announced yesterday (BD: Sep 17, 2013).
Osprey director Dr Chris Nave told Biotech Daily that although the focus was on the Avert trial to reduce cardiac stenting dye use by up to 40 percent, the 'Prospective Randomized Evaluation to Study the Effects of Reduced Contrast Media on the Vitality of the Kidney' (Preserv) trial was "continuing with several existing sites".
Osprey chief executive officer Mike McCormick told Biotech Daily that the company had feedback from doctors that the Avert system sufficiently reduced contrast induced nephropathy in stenting on its own.
The company originally listed on the ASX to develop the Cincor system of capturing the contrast dye used in cardiac angiography procedures to reduce contrast-induced nephropathy (CIN) (BD: Mar 1, 2012).
Mr McCormick told Biotech Daily that Avert and Cincor working together in the Preserv trial delivered more savings of dye to the patient then the Avert alone.
"Doctors in the Preserv [trial] who are using both products together said the Avert component is giving more benefit then the Cincor component and the Avert system is very fast, simple and safe so it is preferred as a standalone device to the combination device in the Preserv," Mr McCormick said.
Mr McCormick said that given the feedback from doctors stating the preference for the Avert device, Osprey wanted to make sure the Preserv trial would allow a contrast-induced nephropathy (CIN) claim on the Avert as a standalone product.
"The FDA urged we needed a different study on Avert only, if we wanted CIN claims on this standalone product …and approved an Avert study that is intended to allow us to add a CIN reduction claim to the already FDA approved Avert product," Mr McCormick said.
"Because the Avert is the product of choice by many cardiologists and the market is very large for Avert we are going to move to enrolling the Avert trial now," Mr McCormick said.
Osprey was up seven cents or 10.8 percent to 72 cents.

IMUGENE

Imugene says it has discontinued development of its fast-melt ibuprofen tablets.
Imugene said it had been developing an ibuprofen tablet that melted in the mouth, which attempted to address issues of unpleasant taste, mouth feel and swallowing difficulties associated with the non-steroidal anti-inflammatory drug ibuprofen.
Imugene executive director Dr Nick Ede said that "testing of our ibuprofen meltlet has been disappointing and hence this project has been discontinued".
"Imugene is now a pharmaceutical business with a drug delivery platform at the centre of its assets," Dr Ede said.
Dr Ede said the Linguet technology showed promise in drugs and food additives that benefited from direct delivery into the blood stream via the buccal and sub-lingual mucosa.
Imugene is developing its technology for a vitamin D 'meltlet' (BD: May 23, Aug 8, 2013).
Imugene fell 0.2 cents or 22.2 percent to 0.7 cents with 109.4 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its October 1, 2013 Bio-Breakfast will investigate the innovation technology jobs of the future and the training required for them.

The Bio-Melbourne Network said that together with the Bio21 Institute it would bring together representatives from education and research, agriculture, health and medical sectors to share their views on the emerging technology occupations.

Bio-Melbourne Network chief executive officer Michelle Gallaher said that the breakfast aimed "to answer how we are preparing our next generation and current working populations to maximize these future job opportunities".

"Technological innovation, together with immense social change and environmental challenges, are shaping future job roles," Ms Gallaher said.

"As emerging research and technology gives rise to new products and experiences, so to does it give rise to entirely new industries and careers," Ms Gallaher said.

The Network said that speakers include Bio21 Institute and the University of Melbourne's Prof Andrew Holmes, the University of Melbourne provost Prof Margaret Sheil, Siemens One-Pacific, head of corporate development Jurgen Schneider, Gardiner Foundation, chief executive officer Mary Harney, former CSL and McKinsey Consulting Dr Rachel David and St Michael's Grammar School head Simon Gipson.

The Network said that the October 1 Bio-Breakfast would be held at the Bio21 Institute, University of Melbourne, 30 Flemington Road, Parkville.

Registration is from 7:15am, followed by a buffet breakfast for a presentation and discussion from 8am to 9:30am.

For more information and to book go to: http://www.biomelbourne.org/events/view/295.