Biotech Daily

Monday October 15, 2012

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: VIRALYTICS UP 15%, PRIMA DOWN 12%**

*** PRIMA PHASE II 'POSITIVE TREND' FOR CVAC FOR OVARIAN CANCER**

*** ALCHEMIA VOTES 99% IN FAVOR OF DEMERGER**

*** GENETIC TECHNOLOGIES FILES 4 MORE US PATENT SUITS**

*** ELLERSTON (PACKER FAMILY) BUYS $10m MORE OF ACRUX**

*** BIONOMICS AGM FOR 1m NEW DIRECTORS' OPTIONS**

*** NUSEP TO SPIN-OUT PRIME BIOLOGICS**

MARKET REPORT

The Australian stock market slipped 0.07 percent on Monday October 15, 2012 with the S&P ASX 200 down 3.2 points to 4,483.4 points.

Ten of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and six were untraded.

Viralytics was the best, was up 3.5 cents or 14.9 percent to 27 cents with 536,374 shares traded.

Anteo climbed 6.25 percent; Antisense was up 5.9 percent; Phylogica and Genetic Technologies were up four percent or more; Impedimed was up 3.3 percent; Tissue Therapies and Universal Biosensors were up more than one percent; with Alchemia, Clinuvel and CSL up by less than one percent.

Prima led the falls, down two cents or 12.1 percent to 14.5 cents with 20.6 million shares traded, followed by Avita down 10 percent to 13.5 cents, with 674,818 shares traded.

Heartware lost 7.3 percent; Benitec and Cellmid fell more than six percent; Compumedics and Sunshine Heart were down more than five percent; Phosphagenics and Prana fell four percent or more; Bionomics, Neuren and Reva were down more than three percent; Biota and QRX shed more than two percent; Mesoblast and Starpharma were down more than one percent; with Acrux, Cochlear, Pharmaxis, Resmed and Sirtex down by less than one percent.

PRIMA BIOMED

Prima says interim phase II trial data shows “a positive trend” for the use of CVac to treat epithelial ovarian cancer patients in remission after first or second line therapy.

The CAN-003 trial data is the first published data since the company’s previous 2006 trial, in which four of 21 patients in the phase II trial at Melbourne’s Austin Hospital had either a clinical response to treatment or stabilization of their disease (BD: May 16, 2006).

Today, Prima said that interim progression free survival data from the CAN003 phase II trial showed a favorable trend toward patients receiving CVac staying in remission longer than those in the observational standard-of-care group.

The company said that combining overall data of first and second remission, the median progression free survival time at the date of data cut-off was 421 days for non-randomized CVac, 365 days for CVac, and 321 days for standard-of-care.

Prima said that the first seven patients were not randomized and all received CVac.

Prima said the data would be presented in a poster by lead author Dr Jeffrey Goh at the International Gynecologic Cancer Society meeting in Vancouver, Canada, tonight October 15, 2012, with a copy of the poster available at: http://www.primabiomed.com.au/announcements/pdf/2012/igcs_poster_oct_2012.pdf.

Prima chief business officer Marc Voigt told Biotech Daily that the CAN003 trial “was meant as an exploratory trial and not meant to be statistically significant”.

“We see what we hoped to see – a clear positive trend,” Mr Voigt said.

“The earlier you treat patients with an immunotherapy the better,” Mr Voigt said.

Mr Voigt said that the patients in the CAN003 trial were in either first or second remission, compared to the previous salvage patients in the 2006 trial and the first remission only patients being recruited for the 800-patient US phase III CANVAS trial (BD: Feb 3, 2012).

The poster concluded: “This summary indicates encouraging trends that CVac may improve the median time to progression for patients.

“In the first three treated patients for which immune monitoring was performed, there were good signals that CVac induced a mucin 1-specific TH1 and cytotoxic type T-cell response,” the poster concluded.

In its media release, Prima said that preliminary intracellular cytokine staining data in three CVac treated patients showed a potent cytotoxic T-cell response specific to mucin 1, while untreated patients did not show the same immune response.

Prima said that on completion of the analysis, it would release intracellular cytokine staining (ICS) data from a cohort of seven patients that had been followed for an extended period and over the next year it would have ICS data on all patients in the CAN-003 trial.

Prima said that CVac could be expected to provide increasing clinical benefit to patients as the immune system took time to build-up its strongest response against tumor cells.

The company said that interim progression free survival and immune monitoring data from the trial showed an early profile similar to other successful immunotherapy products to treat cancer such as Provenge and Yervoy.

Dr Goh said the initial immune monitoring data were “representative of the type of response necessary to mount an effective immune response against cancer”.

“And the trends in progression free survival are very encouraging,” Dr Goh said.

“This interim dataset is consistent with expectations for a potentially effective immune therapy to treat ovarian cancer,” Dr Goh said.

Prima chief executive officer Matthew Lehman said the “promising CAN-003 data further validate our ovarian cancer program and the CANVAS trial”.

“We will be evaluating the potential to explore CVac in other cancer types that over-express mucin 1 as well,” Mr Lehman said.

Prima fell two cents or 12.1 percent to 14.5 cents with 20.6 million shares traded.

ALCHEMIA

Alchemia says that 99.01 percent of votes and 95.91 percent of shareholders have supported the demerger of Audeo Oncology.
Alchemia said that all votes relating to the demerger were passed by more than 99 percent of the voting shares.
The company said it would seek orders for the Federal Court at a hearing scheduled for October 17, 2012.
Alchemia said the scheme of demerger would become effective on October 18, when the Court orders were expected to be lodges with the Australian Securities and Investments Commission, but the scheme would not be implemented until the fundraising and initial public offering were completed by December 31, 2012.
Alchemia was up half a cent or 0.85 percent to 59.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says that with patent law firm Sheridan Ross PC, it has filed four more patent infringement suits relating to its non-coding DNA technologies.
Genetic Technologies said that it had filed legal action against Genesis Genetics Institute LLC in the US District Court for the Eastern District of Michigan Southern Division; Genetics & IVF Institute Inc on the District Court for the Eastern District of Virginia; Reprogenetics LLC in the District Court for the District of New Jersey; and Medical Diagnostic Laboratories LLC in the District Court for the District of New Jersey.
Genetic Technologies earned $2,526,599 in licencing revenue in the year to June 30, 2012 and in what the company described as “an exceptional year” earned $13,680,741 in the year to June 30, 2011 (BD: Aug 28, 2012).
Genetic Technologies was up half a cent or 4.55 percent to 11.5 cents.

ACRUX

Ellerston Capital has increased its substantial shareholding in Acrux from 10,962,096 shares (6.58%) to 14,237,169 shares (8.65%).
Ellerston said that it bought and sold Acrux shares between August 9 and October 12, with the single largest transaction the acquisition of 1,000,000 shares for $3,561,400 on October 12, 2012.
Ellerston became a substantial shareholder in May, 2012, saying the shares were held by HSBC Custody Nominees, Cogent Nominees, JPM Nominees and National Nominees (BD: May 23, 2012).
In August, Ellerston provided a detailed list of “passive substantial holders” related body corporates of the principal person, including Arctic Asia, Australian Financial Times, Conpress (Hong Kong, Malaysia, Cayman, Christchurch, Finance, Holdings, International Finance) and Consolidated Press Property, a raft of Ellerston companies, as well as Hoyts Cinemas (America, Argentina, Chile, Germany, Polska), Park Street Partners Cayman and Perisher Village Developments, among others (BD: Aug 8, 2012).
Ellerston’s website said that it was a subsidiary of Consolidated Press Holdings, a private company of the Packer media and gambling family.
Acrux fell two cents or 0.6 percent to $3.58 with 849,345 shares traded.

BIONOMICS

Bionomics shareholders will vote to issue 500,000 options each, exercisable at 32 cents, to recently appointed directors chairman Graeme Kaufman and Dr Jonathan Lim.
Bionomics said the options would be exercisable in five tranches of 100,000 options each over the next six years, with a lifespan of five years from the date of issue.
Mr Kaufman was appointed a director last month and last week the company said he would become chairman at the annual general meeting (BD: Sep 18, Oct 11, 2012).
Last month, Bionomics said it would appoint Dr Lim as a director when it acquired the Biogen Idec spin-out, Eclipse Therapeutics, which Dr Lim co-founded, for about $8-10 million in scrip to develop drug candidates targeting cancer stem cells (BD: Sep 17, 2012).
Bionomics said shareholders would also vote on the issue of 65,000 options exercisable at 28.7 cents within five years of issue to chief executive officer Dr Deborah Rathjen, as well as ratify a prior placement and vote on the election of Dr Lim and Mr Kaufman and the re-election of director Trevor Tappenden.
The meeting will be held in the Marble Room at the Radisson Blu Plaza Hotel, 27 O'Connell Street, Sydney, on November 14, 2012 at 11am (AEDT).
Bionomics fell one cent or three percent to 32 cents.

NUSEP

Nusep says it will spin out its therapeutic plasma fractionation business, Prime Biologics, subject to shareholder approval.
Nusep said the spin-out would reduce expenditure and leave the company with two new highly profitable revenue streams.
The company said the spin-out of Prime Biologics enabled it to focus on development of new Prime technology applications including in-vitro fertilization, recombinant proteins and renal dialysis, while generating the first of a series of high margin revenue streams.
Nusep said that Prime Biologics used its Prime technology in its therapeutic plasma manufacturing process.
The company said that Prime Biologics's goal was to open up the Asian therapeutic plasma market and the untapped currently unprocessable plasma market.
Nusep said the goals and business plans for both companies were significantly different and required different operational focus.
Nusep said it had been difficult to finalize the external funding for Prime Biologics while it formed part of the Nusep group as it had a market capitalisation of less than $10 million relative to the $46 million valuation of Prime Biologics.
Nusep said it held 90 percent of Prime Biologics and 10 percent by Luye Pharma Group and following an initial public offer Luye Pharma would hold 20 percent, an investor group would hold 10 percent, escrow Nusep shareholders would hold 50 percent, Nusep would hold 10percent and the offer would raise 10 percent.
The company said that the funds raised from the sale of the Prime Biologics shares would be retained in Prime Biologics and be used to produce the first registered therapeutic product using the Prime technology.
Nusep said that as part of the spin-off all escrow shares would be distributed pro rata to its shareholders on a one-for-five basis, representing 50 percent of Prime Biologics.
Nusep was up half a cent or 6.7 percent to eight cents.