Biotech Daily

Monday October 19, 2015

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: REVA UP 9%; OSPREY DOWN 55%**

*** OSPREY TUMBLES 72% ON AVERT NEPHROPATHY FAILURE**

*** NOVOGEN: 'CANTRIXIL, PLATINUM STOPS OVARIAN CANCER' IN MICE**

*** ST VINCENT'S INSTITUTE HOSTS TRANSPLANT MEETING**

*** WEHI'S DR EWA MICHALAK WINS NBCF $680k**

*** KOMA TO DISTRIBUTE ANTEO MIX&GO IN SOUTH KOREA**

*** UNILIFE BORROWS $14m MORE, CUTS STAFF, EXECUTIVE PAY**

*** VIRALYTICS AGM FOR 5.7m MORE DIRECTOR OPTIONS**

*** BENITEC APPOINTS HEPATOLOGY ADVISORY BOARD**

*** PROTEOMICS APPOINTS JAMES MOSES DIRECTOR, WA EXPORT GONG**

MARKET REPORT

The Australian stock market was flat on Monday October 19, 2015, with the ASX200 up 1.5 points to 5,269.7 points. Ten of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and five were untraded.

Reva was the best, up eight cents or 9.3 percent to 94 cents, with 244,168 shares traded.

Benitec climbed 5.95 percent; Pro Medicus was up 4.1 percent; Medical Developments improved 3.5 percent; Acrux, Ellex and Psivida rose more than two percent; Mesoblast, Resmed and Sirtex were up more than one percent; with Impedimed and Cochlear up by less than one percent.

Osprey led the falls, down as much as 71.6 percent to 19 cents before closing down 37 cents or 55.2 percent at 30 cents with 11.8 million shares traded.

Atcor lost 9.1 percent; Actinogen fell 6.35 percent; Tissue Therapies and Universal Biosensors were down more than five percent; Prana fell four percent; Biotron, IDT and Polynovo were down more than three percent; Anteo shed two percent; Admedus, Circadian, Clinuvel, Compumedics, Neuren and Orthocell were down one percent or more; with Bionomics, CSL and Nanosonics down by less than one percent.

OSPREY

Osprey fell as much as 71.6 percent to 19 cents on news that its 578-patient trial of the Avert system failed to reduce contrast-induced nephropathy (CIN).

Osprey said that there were 76 CIN events in the Avert arm and 74 in the control arm but the trial achieved three US Food and Drug Administration expanded claims of dye savings, image quality and reflux reduction (BD: Jul 16, 2015).

In July, Osprey said it was seeking five additional claims of dye savings, reflux reduction, image quality, contrast-induced nephropathy reduction and hospital cost savings.

In 2012, Osprey raised $20 million and listed on the ASX to commercialize the Baker IDI Heart and Diabetes Institute-invented Cincor cardiac contrast dye reduction and removal system (BD: Mar 1, May 2, 2012).

Osprey chief executive officer Mike McCormick told Biotech Daily at that time of the 3.2 million patients world-wide undergoing angioplasty or stenting, “25 percent have pre-existing chronic kidney disease” and were at risk of contrast-induced nephropathy, a form of kidney damage caused by the toxic dye used in the procedures and the Cincor system was designed to capture the dye from the heart before it circulated to the kidneys.

In 2012, Osprey said the Cincor system had Conformité Européenne (CE) mark approval and initial trials showed it reduced the risk of contrast-induced nephropathy by 50 percent.

But in 2013, Osprey moved its focus from the Cincor system to the Avert system which it said had US FDA 510(k) pre-market approval and reduced the amount of dye by up to 40 percent without compromising image quality (BD: Oct 31, 2012; Aug 23, 2013).

Today, Osprey said that based on interim data, it received FDA clearance on October 15, 2015 for the three claims of dye savings, image quality and reflux reduction and full US commercialization would be brought forward to this year.

The company said that the trial was completed on time and on budget and showed that the Avert system reduced the amount of dye injected to the patient by 15 percent, compared to a randomized control group.

The company said that “it was assumed that the difference in amount of dye used in the treatment group as compared to the control group would approximate actual dye savings that is achieved with Avert in each case, 30 percent to 40 percent”.

“In the trial we observed the difference in dye used was lower than our average Avert dye savings per case due to differences in mix of procedure types, angiogram versus [percutaneous coronary intervention, or stenting] performed in control group versus Avert group,” Osprey said.

The company said that, on average, stenting used almost twice as much dye as angiogram procedures, with 67ml compared to 130ml, respectively and patients were randomized between the control and Avert groups prior to the known procedure type.

Osprey said that the Avert group had more stenting procedures compared to the control group, there were differences in complexity of procedure performed, the Avert group had an increased number of complex, multi-vessel, cases as compared to the control and the range of dye required per case was widely variable and not predictable.

The company said that further evaluation of the full data cohort including CIN sub-group analysis would be performed by a steering committee of academic, key opinion leading physicians in November, with results by July 2016.

Osprey said its Avert system was “the only product proven to reduce contrast volumes without compromising image quality cleared by the FDA [and] the new expanded claims, including for dye savings, now enable physicians to comply with cardiology and radiology society guidelines that urge physicians to use dye-sparing approaches with at-risk patients”.

Osprey closed down 37 cents or 55.2 percent to 30 cents with 11.8 million shares traded.

NOVOGEN

Novogen says that Yale University animal data suggests that Cantrixil may have utility in recurrent ovarian cancer when dosed in combination with platinum-based drugs.

Novogen said the data was presented by Yale Medical School's Dr Ayesha Alvero at the American Association for Cancer Research 'Advances in Ovarian Cancer Research: Exploiting Vulnerabilities' meeting in Orlando Florida on October 18, 2015.

In March, Novogen said Cantrixil was "highly effective at killing human ovarian stem [or tumor-initiating] cells" in mice (BD: Mar 30, 2015).

Today, Yale University's Prof Gil Mor said that previous studies had shown that conventional chemotherapy was "not effective against ovarian cancer stem cells and cannot prevent recurrence [and] our finding that Cantrixil, by targeting [ovarian cancer stem cells], can prevent recurrence in-vivo as maintenance therapy or in combination with chemotherapy provides an opportunity for developing new therapeutic strategies that may improve survival in ovarian cancer patients".

Novogen chief scientific officer Dr David Brown said the data report was the completion of the designated pharmacology studies demonstrating Cantrixil proof-of-concept.

Dr Brown said that following a final safety review and approval of the phase I trial protocol by Novogen's Cantrixil committee, the company would submit documentation to begin a phase I trial in Australia in 2016 and open a US phase I trial site once Cantrixil had investigational new drug application status from the US Food and Drug Administration.

Novogen said the Yale research found that intra-peritoneal administration of 100mg/kg Cantrixil as a first-line therapy in combination with cisplatinum or paclitaxel, improved survival compared with the monotherapy controls ($p < 0.001$) and Cantrixil, given as maintenance therapy following paclitaxel treatment was able to retard the onset of recurrent disease ($p = 0.002$).

Novogen was up 0.5 cents or 3.3 percent to 15.5 cents with 2.5 million shares traded.

ST VINCENT'S INSTITUTE

St Vincent's Institute director Prof Tom Kay says that his Institute will host an international transplant meeting to be held in Melbourne, November 15-19, 2015.

The St Vincent's Institute said that the 2015 Joint Congress of the International Pancreas and Islet Transplant Association (IPITA), the International Xenotransplantation Association (IXA) and the Cell Transplant Society (CTS) "reaffirms their strong partnership as leaders in transplantation".

The Institute said that the congress "promises to provide an outstanding and informative program" and Prof Kay said it would be an "excellent opportunity for local and international delegates to interact with a wide range of experts in the transplantation field".

The St Vincent's Institute said that scientific program chair Prof Peter Cowan, had developed a program "featuring world-renowned speakers in the complementary fields of transplantation, stem cell biology, regenerative medicine and bioengineering".

The Institute said speakers would include Oklahoma Medical Research Foundation chair in cardiovascular research Dr Charles Esmon, the southern Germany-based University of Regensburg's Ed Geissler, Mesoblast chief executive Prof Silviu Itescu the University of Pennsylvania's Prof John Lambris, the University of Queensland's Melissa Little Australian Regenerative Medicine Institute director Prof Nadia Rosenthal, Indiana University chief of transplantation Dr Joe Tector and the University of Wollongong's Prof Gordon Wallace.

The Institute said that the Joint Congress would be held at the Melbourne Convention and Exhibition Centre, November 15-19, 2015.

To register, go to: www.melbourne2015.org.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that Dr Ewa Michalak has received $680,000 from the National Breast Cancer Foundation for breast cancer research.
The Institute said that Dr Michalak was researching breast stem cells with the potential to understand better how breast cancer spreads and could lead to better treatments.

ANTEO DIAGNOSTICS

Anteo says it has a non-exclusive distribution agreement with the Seoul, South Korea-based Koma Biotech to market, distribute and support Mix&Go in South Korea.
Anteo said that Mix&Go was its core nano-glue product range and was undergoing early stage commercialization.
The company said that the agreement with Koma was “a further strategic step in developing a strong sales channel into South Korea”.
Anteo said that Koma was a manufacturer and supplier of reagents and tools for life science research, had been operating in the Korean market since 1994,
The company said that Koma was a distributor of Luminex in the South Korean region, and the agreement was expected to provide Luminex customers with easier access to the Mix&Go activation kit for multiplex microspheres, together with the 200nm and 1um coupling kit products.
Anteo fell 0.2 cents or two percent to 9.7 cents with 1.2 million shares traded.

UNILIFE CORP

Unilife says it will borrow up to an additional $US10 million ($A13.8 million) from Orbimed affiliate Royalty Opportunities SÀRL.
Last year, Unilife said it had a $US60 million debt financing agreement with the New York-based Orbimed and later said it had “completed” its at-the-market equity draw-down facility with Cantor Fitzgerald issuing 5,811,800 shares of US common stock for $US12.4 million. (BD: Mar 14, Aug 4, 2014).
Today, Unilife said it had implemented an additional cost reduction initiative beyond last year’s 17 percent reduction of its workforce with a further reduction of about 20 employees, or eight percent of its workforce.
The company said that executive chairman Alan Shortall had agreed to a 100 percent reduction of his base salary and the elimination of perquisites, to December 31, 2015.
The Unilife October 5, 2015 notice of annual general meeting said that in the 2014 financial year Mr Shortall received a salary of $US420,000 and a bonus of $US210,000 and for the 2015 financial year received $US420,000 in salary, $420,000 in bonus and $US7,540,000 in stock awards.
Unilife said that chief financial officer David Hastings, chief operating officer Dr Ramin Mojdeh, general counsel and secretary John Ryan and chief accounting officer Dennis Pyers agreeing to a 50 percent reduction in their base salaries and the elimination of perquisites to December 31, 2015.
Unilife said that other senior employees had agreed to a reduction in their base salaries to December 31, 2015.
The company said that the measures were expected to reduce expenses, net of severance costs, by $US700,000 to December 31, 2015.
Unilife fell four cents or 16 percent to 21 cents with 1.9 million shares traded.

VIRALYTICS

Viralytics will vote to grant 5,000,000 options to chief executive officer Dr Malcolm McColl, with 700,000 options for three directors.
Viralytics said that shareholders would vote to issue 300,000 options for chairman Paul Hopper and 200,000 options to directors Peter Turvey and Dr Len Post.
The company said Dr McColl's options would vest in two tranches, exercisable at 58.85 cents within five years and the director options would vest in three tranches, exercisable within five years at the 5-day volume-weighted average price to the day of issue.
Last year, 19.5 percent of Viralytics voting shareholders opposed the grant of 1,200,000 options to Dr McColl, Mr Turvey, Mr Hopper and Dr Len Post (BD: Nov 27, 2014).
Today, Viralytics said that of the non-executive directors' fee pool of $500,000, $252,941 was used in the year to June 30, 2015 and if the company was "unable to issue options then it may need to consider whether, in order to attract and retain appropriate directors, it needs to increase the level of cash fees payable".
The company's notice of meeting said shareholders would vote on the remuneration report, renewing the 10 percent placement capacity and the re-election of Dr Post.
The meeting will be held at McCullough Robertson, Level 32, MLC Centre, 19-29 Martin Place, Sydney on November 18, 2015 at 11am (AEDT).
Viralytics was unchanged at 56 cents.

BENITEC BIOPHARMA

Benitec says it has formed a hepatology clinical advisory board as a strategic resource as it develops therapies for the treatment of hepatitis B and C.
Benitec said the board included and the University of Sydney and Royal Prince Alfred Hospital's Prof Geoffrey McCaughan, the Toronto, Ontario-based University Health Network's Prof Harry Janssen and Prof Keyur Patel.
Benitec was up 2.5 cents or 5.95 percent to 44.5 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has appointed James Moses as an executive director, effective from today and starting on a salary package of $80,000 a year including statutory superannuation.
Proteomics said Mr Moses had experience in investment markets and the media "developed in a career spanning 25 years, including a wealth of expertise in advising emerging small-cap public companies".
The company said Mr Moses was the managing director of a small-cap focused investor relations and corporate communications practice and had a track record in advising a wide range of companies, including in the life sciences and bio-technology sectors.
Proteomics said Mr Moses' career began in the investment market, where he worked for 15 years in business development roles for fund managers, and as a private client adviser for an investment advisory firm, and he previously worked as a business and finance journalist and editor for business and industry publications.
Separately, Proteomics said it had won the Western Australia Government health and biotechnology export award.
Proteomics climbed five cents or 19.2 percent to 31 cents.