Biotech Daily

Thursday October 22, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: BENITEC UP 27%; USCOM DOWN 9%**

*** BENITEC TT-034 FOR HEP C REACHES LIVER, NO ADVERSE EVENTS**

*** WALTER REED TREATS FIRST AVITA RECELL TRAUMA PATIENT**

*** PHOSPHAGENICS HIRES TESA LABTEC FOR TPM-OXYMORPHONE PATCH**

*** SOMNOMED SELLS 250k ANTI-SNORING MOUTHGUARDS, COMPLIANCE**

*** SIMAVITA SIGNS 2,500 NORTH AMERICAN INCONTINENCE BEDS**

*** SUN NAME CHANGE TO DIMERIX AGM**

*** GRANDLODGE, PETER ANASTASIOU TAKE 14% OF IMMURON**

*** HUNTER HALL TAKES 15% OF AVITA**

*** ONCOSIL APPOINTS TOM MILICEVIC CFO, CO SEC**

MARKET REPORT

The Australian stock market was up 0.3 percent on Thursday October 22, 2015, with the ASX200 up 15.5 points to 5,263.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and two were untraded.

Benitec was the best, up 12 cents or 27.3 percent to 56 cents with 1.3 million shares traded, followed by Genetic Technologies up 11.8 percent to 1.9 cents with 1.5 million shares traded.

Osprey climbed 7.4 percent; Oncosil and Polynovo were up more than three percent; Impedimed, Living Cell and Neuren rose more than two percent; Anteo, Atcor, Bionomics and Clinuvel were up one percent or more; with CSL, Orthocell and Resmed up by less than one percent.

Uscom led the falls, down 1.5 cents or 8.6 percent to 16 cents with 267,844 shares traded, followed by Circadian down 8.5 percent to 27 cents with 22,300 shares traded.

Actinogen, Ellex and Pro Medicus fell more than four percent; Prima lost 3.3 percent; Compumedics, Nanosonics, Optiscan and Pharmaxis shed more than two percent; Acrux, Admedus, Tissue Therapies and Universal Biosensors were down more than one percent; with Cochlear, Medical Developments, Sirtex and Starpharma down by less than one percent.

BENITEC BIOPHARMA

Benitec says that data on four patients in its phase I/IIa trial of TT-034 for hepatitis C shows that the drug is reaching the liver with no reported serious adverse events.

Benitec said that the interim data would be presented at the American Association for the Study of Liver Disease meeting to be held in San Francisco, California from November 13 to 17, 2015 and the abstract was available, among the published abstracts, at: http://www.aasld.org/sites/default/files/TLM-2015-LakeBreakingAbstracts.pdf.

The company said that the primary endpoint of the study was safety and the three doses of TT-034 administered to date had been well tolerated and there had been no reported serious adverse events related to administration of the study drug.

Benitec said the initial dose of 4.0 x 10^{11} vector genome particle per kilogram (vg/kg) resulted in very low levels of transduction as expected, with the second dose of 1.25 10^{11} vg/kg resulted in the detection of higher levels of TT-034 in the hepatocytes, the predominant cell type in the liver, yielding 0.48, 3.65 and 10.44 copies of TT-034 DNA per cell in the three patients respectively, while the first subject administered with the third dose of 4.0 10^{11} vg/kg had 17.74 copies of TT- 034 per cell, indicating that a significant portion of their hepatocytes had been transduced and expression of anti-hepatitis C short hairpin RNA (shRNA) was clearly detected in the transduced hepatocytes.

Benitec chief scientific officer Dr David Suhy said the results “show that a single infusion of TT-034 is reaching the liver and that it has a very favourable safety profile at the doses tested to date”.

“In the patient that has received the highest dose to date, we are able to detect that [anti-hepatitis C] shRNAs have been expressed in the liver without any drug-related serious adverse effects, indicating that so far the trial is achieving its primary outcome,” Dr Suhy said.

Benitec climbed 12 cents or 27.3 percent to 56 cents with 1.3 million shares traded.

AVITA MEDICAL

Avita says that the first of up to 20 patients has been treated in a trial of Recell for traumatic wounds suffered by civilians and wounded military personnel.

Avita said that it had an advisory role at the US Department of Defense research program-funded, randomized, within-patient controlled, feasibility trial at the Bethesda, Maryland-based Walter Reed National Military Medical Center.

The company said that the trial was led by principal investigator Dr Peter Rubin and the investigator-initiated trial was aimed at evaluating whether Recell combined with widened split-thickness skin grafts was more effective in treating full-thickness traumatic wounds than conventional skin grafts.

Avita said that outcomes for the area treated with the Recell regenerative epithelial suspension would be compared to outcomes of another area on the same patient treated with only conventional meshed auto-grafting.

Avita said that previous use of Recell at Walter Reed under compassionate use dispensations granted by the US Food and Drug Administration included treatment of soldiers wounded in Afghanistan and Iraq and the July-August 2015 issue of Army Technology Magazine reported that the Recell device “was regarded as having great potential for treating burn injuries among US military personnel”.

The company said that the Recell device, being fully portable, battery-powered and needing only ambient storage temperatures, was well-suited for deployment in field hospitals.

Avita was unchanged at 11 cents.

PHOSPHAGENICS

Phosphagenics says the Lagenfeld, Germany-based Tesa Labtec GmbH will help develop its transdermal tocopheryl phosphate mixture (TPM) oxymorphone patch.

Phosphagencis said that Tesa Labtec was a transdermal formulation specialist and the development agreement would “build on the work done to date and create a transdermal patch product with suitable characteristics for development through to commercialization”.

In 2012, Phosphagenics turned to the then Labtec for assistance with its TPM-oxycodone patch, which was originally being developed by the St Paul, Minnesota-based 3M Corp (BD: Nov 16, 2010; May 23, 2011, May 23, 2012).

Today, Phosphagenics said that once formulated, the patch would be progressed towards an investigational new drug application with the US Food & Drug Administration.

The company said that the TPM-oxycodone patch was in a phase II proof-of-concept study for post-herpetic neuralgia (BD: Apr 17, 2015).

Phosphagenics chief executive officer Dr Ross Murdoch said the company “assessed proposals from several potential partners before selecting Tesa”.

“We have confidence in their specialist skills and in their ability to complete the reformulation to a standard that will enable us, or a partner, to advance the program to commercialization,” Dr Murdoch said.

“Our previous work with TPM and oxymorphone has already demonstrated that it is possible to achieve impressive transdermal delivery and plasma levels within the recognised therapeutic range,” Dr Murdoch said.

“This collaboration is designed to take that accumulated know-how and build it into a patch with all the desirable characteristics necessary for successful commercialisation by ourselves or potential partners,” Dr Murdoch said.

Phosphagenics was unchanged at 1.5 cents.

SOMNOMED

Somnomed says it has passed the milestone of having fitted more than 250,000 patients with its Somnodent anti-snoring mouthguard devices.

Somnomed said that about 140,000 patients lived in the US and Canada, 70,000 in Europe and 40,000 in the Australia-Pacific region.

The company said that it took seven and a half years to reach 180,000 customers, but “only a further 16 months to exceed the 250,000 patients milestone”.

Somnomed executive chairman Dr Peter Neustadt said it was “an important event in Somnomed’s history”.

“It is not only a sign of the success of our treatment and the rapidly growing acceptance of our [continuous open airway therapy] alternative to [continuous positive airway pressure], it is a very important element in proving the medical history Somnomed has created over the years,” Dr Neustadt said.

“Somnomed is proud that it has been able to provide an effective, safe and more patient friendly treatment of obstructive sleep apnoea … than is otherwise available,” Dr Neustadt said.

Somnomed said that using its Somnodent Dentitrac compliance system it found that patients were “highly compliant” with 95 percent using the system for four hours minimum per night on 21 nights a month compared to a generally reported rate of 60 to 70 percent for continuous positive airway pressure (CPAP) devices.

Somnomed was up five cents or two percent to $2.53.

SIMAVITA

Simavita says its North American distributors have executed agreements for its smart incontinence management system covering 2,500 beds.

Simavita said that the agrements covered 1,200 beds in the US including an Alabama 225 bed long term care facility which specialises in rehabilitation services, 155 beds in a Maryland nursing facility and a 27-facilty, 820-bed group in Colorado, as well as the first Canadian contract for a nine-facility nursing home chain in Ontario covering more than 1,300 beds.

Simavita chief executive officer Philippa Lewis said that it was “tremendously encouraging that our local sales and marketing team has been able to convert a number of high quality customers so quickly”.

The company said that five pilot studies representing 36 facilities and more that 3,700 beds had completed a trial of the technology in conjunction with US distribution partner Medline and had progressed to contract negotiation phase.

Simavita said that a further set of pilot studies was planned, with one in the assisted living segment of aged care, the fastest growing aged care market in the US and used by individuals who needed little or no help and live in separate apartments with shared communal areas.

Simavita was unchanged at 42.5 cents.

SUN BIOMEDICAL, DIMERIX BIOSCIENCE

Sun shareholders will vote on a resolution to change the company’s name to Dimerix and its ASX code from SBN to DXB.

Earlier this year, Sun acquired Dimerix and appointed Dimerix founder Dr James Williams as its executive chairman to develop DMX200 its phase II combination drug for diabetic kidney disease and other assets (BD: Jun 4, Sep 29, Nov 25, 2014; May 13, Jul 3, 2015).

Sun said that other resolutions to the meeting included approval; of the 10 percent placement capacity, the re-election of director Howard Digby and approval of the remuneration report.

The meeting will be held at Level 2, 1 Walker Avenue, West Perth, Western Australia, on November 26, 2015 at 11.30am (AWST).

Sun was unchanged at 0.8 cents.

IMMURON

Grandlodge and Immuron executive vice president Peter Anastasiou have increased their holding from 9,409,500 shares (12.61%) to 10,698,360 shares (14.11%).

Since the previous substantial announcement, Immuron has held a 40-to-one stock consolidation (BD: Nov 20, 2014).

Today, Mr Anastasiou said that through Advanced Clinical Systems International the group acquired 328,124 shares at no cost as approved by general meetings and Grandlodge acquired 120,000 shares for $60,000 or 50 cents a share.

Mr Anastasiou said that, with Kristine Patricia Anastasiou, he acquired 284,736 shares for $61,879 or 21 cents a share.

The substantial shareholder notice said that through National Nominees the group bought 556,000 shares for $209,056 or 37.6 cents a share.

Immuron was untraded at 51 cents.

AVITA MEDICAL

Hunter Hall Investment Management says it has become a substantial shareholder in Avita with 80,129,032 shares (15.04%).

The Sydney-based Hunter Hall said that from March 13 to October 19, 2015 it bought the 80,129,032 shares for $6,952,000 or 8.7 cents a share, with the most recent acquisition on October 19, of 64,000,000 shares for $5,952,000 or 9.3 cents a share, the price in the recent $10 million placement (BD: Oct 20, 2015).

ONCOSIL MEDICAL

Oncosil says it has appointed Tom Milicevic as chief financial officer and company secretary, effective from today, October 22, 2015.

Oncosil said that Mr Milicevic would replace joint company secretaries Peter Casey and Nicholas Falzon who will continue with the company to ensure a smooth transition.

The company said that Mr Milicevic had more than 20 years' experience and had financial expertise in medical device and biotechnology companies, most recently as chief financial officer and later chief executive officer with Advanced Surgical Design and Manufacture, now Allegra Orthopaedics, taking the company through its initial public offer and ASX listing in 2007.

Oncosil said that previously Mr Milicevic was Babcock & Brown Residential Land Partners' chief financial officer where he was the financial lead on the stapled security's $175 million initial public offer, and before that was the chief financial officer and company secretary with Avantogen and held finance and accounting roles with Cochlear, Boral and Smorgon Steel.

The company said that Mr Milicevic held a Bachelor of Commerce from the University of Western Sydney.

Oncosil was up half a cent or 3.3 percent to 15.5 cents.