Biotech Daily

Monday July 6, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AVITA UP 9%; BIOTRON DOWN 18%**

*** VALE ALASTAIR LUCAS**

*** AVITA: 'RECELL REPIGMENTS VITILIGO AND PIEBALDISM 78%'**

*** DSMC TELLS BIOTRON: 'FOCUS ON BIT225 COMBINATION, GENOTYPE 3'**

*** SIMAVITA SIGNS PAUL HARTMANN FOR AUSTRALIAN DISTRIBUTION**

*** PHYTOTECH APPLIES FOR ISRAEL MARIJUANA TRIALS FOR MS**

*** ANALYTICA TRADING HALT, PLEADS FUNDING TO ASX 80% QUERY**

*** ORTHOCELL PLEADS SCHULTZ TO ASX 15% QUERY**

*** RA CAPITAL 'TRIMS' TO 9% OF BENITEC**

*** MATTHEW CALLAHAN, SRV TAKE 6% OF SUN**

*** RHINOMED APPOINTS CHRIS FROOME TURBINE 'AMBASSADOR'**

*** USCOM APPOINTS STEPHEN WILSON US BUSINESS DEVELOPMENT**

MARKET REPORT

The Australian stock market lost 1.14 percent on Monday July 6, 2015 with the ASX200 down 63.3 points to 5,475.0 points. Nine of the Biotech Daily Top 40 stocks were up, 22 fell, five traded unchanged and four were untraded.

Avita was the best, up 0.7 cents or 9.1 percent to 8.4 cents with 421,866 shares traded. IDT climbed 6.5 percent; Optiscan was up 5.9 percent; Psivida and Uscom were up more than three percent; Admedus and Neuren rose more than two percent; with Medical Developments and Universal Biosensors up more than one percent.

Biotron led the falls, down 2.5 cents or 17.9 percent to 11.5 cents with 5.1 million shares traded. Genetic Technologies and Pharmaxis lost more than six percent; Actinogen, Bionomics and Starpharma fell more than five percent; Anteo and Antisense fell more than four percent; Cellmid, Nanosonics, Prana and Prima were down more than three percent; Atcor, Benitec, Impedimed, Living Cell, Mesoblast, Oncosil, Osprey, Sirtex and Viralytics shed two percent or more; with Cochlear and CSL down more than one percent.

ALASTAIR LUCAS

Former Burnet Institute chairman and Research Australia director Alastair Lucas has died.
Research Australia chair Prof Christine Bennett and Burnet Institute deputy director Prof David Anderson told Biotech Daily that Mr Lucas died earlier today, aged 63 years.
Last year, the Burnet Institute said Mr Lucas would take extended leave "after being unexpectedly diagnosed with a serious illness over the weekend" and he would take leave as Medical Research Future Fund Action Group chairman and Goldman Sachs Australia investment banking chairman (BD: Sep 10, 2014).
Today, Prof Bennett said that Mr Lucas was a Research Australia director from 2012 to 2014 and chairman of the Burnet Institute from 2002 to 2014 and was "a tireless, visionary and passionate advocate for medical research, public health and animal rights".
"His legacy in the drive for the Medical Research Future Fund and also the establishment of a national philanthropic medical research fund which is a still unfinished story is very real and recognised by us all," Prof Bennett said.
Burnet director and chief executive officer Prof Brendan Crabb said last month that Mr Lucas's contribution to the Burnet and Australian public life had been exemplary and the Order of Australia honor was "richly deserved".
"Alastair helped steer Burnet through many challenges over the 12 years of his tenure as chair and also set a great example as a major donor," Prof Crabb said.
"Through his strategic advice and financial acumen, Burnet has established a global reputation for excellence across research and public health activities," Prof Crabb said.
"Alastair's exemplary leadership throughout the health and medical research sector has saved and improved the lives of many people."

AVITA MEDICAL

Avita says that last year's 10-patient vitiligo and piebaldism trial showed Recell repigmented 78 percent of treated sited compared to zero percent control sites.
In 2014, Avita said the randomized, within-subject controlled pilot trial, facilitated by the Netherlands Institute for Pigment Disorders, of Recell for patients with depigmented skin lesions showed statistically significant results (BD: Jun 11, 2014).
Today, the company said that median repigmentation in the 10 patients was 78 percent for sites treated with Recell six months post-treatment, compared to zero percent for each of the two control sites for the same time-frame ($p = 0.001$).
Avita said that 70 percent of the sites treated with ReCell showed greater than 73 percent repigmentation of their depigmented test lesion and patients were satisfied with Recell, with 70 percent assessing Recell site repigmentation as good or excellent.
Avita said that Recell was well-tolerated and patients did not experience any long term side effects, infections or treatment-area scars.
The trial, entitled 'Autologous cell suspension transplantation using a cell extraction device in segmental vitiligo and piebaldism patients: A randomized controlled pilot study was published in the Journal of the American Academy of Dermatology and is at: http://eblue.org/article/S0190-9622(15)01451-6/fulltext.
Avita chief executive officer Adam Kelliher said that the application of the regenerative epithelial suspension created in the Recell device was "shown to be a safe and effective treatment for conditions linked to pigmentation".
Avita head of research and technology Andrew Quick the company was "pleased to see results showing superior clinical outcomes with Recell in robust studies with rigorous designs".
Avita was up 0.7 cents or 9.1 percent to 8.4 cents.

BIOTRON

Biotron says its data and safety monitoring committee has recommended that future BIT225 hepatitis C trials focus on genotype 3 patients in combination with other drugs.

Biotron said the recommendation followed a review of interim, preliminary data from its 60-patient, three-month dosing phase II trial of BIT225 for hepatitis C genotypes 1 or 3 in Thailand, designed to extend efficacy data and confirm BIT225's safety and tolerability in longer term dosing with a capsule formulation (BD: Dec 3, 2014).

Today, Biotron said that the US-based data and safety monitoring committee (DSMC) recommended that it focus of genotype 3 patients and treatment with BIT225 in combination with direct-acting antiviral drugs.

The company said that current direct-acting antiviral drug therapies for this group involved treatment for up to 24 weeks and response rates were lower than for other hepatitis C genotypes.

Biotron said the recommendation was in-line with its strategy to focus on specific hepatitis C patient groups and it had been progressing towards filing an investigational new drug application with the US Food and Drug Administration for a trial of BIT225 in combination with one or more direct-acting antiviral drugs in genotype3 patients.

Biotron said the phase II trial dosed patients at 400mg of BIT225 twice daily for three months in combination with pegylated interferon alfa 2b and ribavirin, before continuing to receive standard of care to 24 weeks for genotype 3 or 48 weeks for genotype 1.

The company said the DSMC reviewed preliminary safety data for all subjects to week 12 of the trial and the adverse events were in-line with those seen in previous trials.

Biotron said the Committee noted that more subjects in the BIT225 arms withdrew from the study than in the placebo arms and while investigations were ongoing, the withdrawals were "likely to be related to the higher than expected drug exposure with the new, capsule formulation used in this study, compared to the formulation used in previous studies".

The company said that safety and pharmacokinetic data from the trial were key to determining the dose of BIT225 for future studies and while modelling of the data was in progress, future doses were expected to be less than used in this trial.

Biotron said the Committee reviewed preliminary data on the antiviral effect of BIT225 and at the completion of dosing with either BIT225 or placebo with interferon and ribavirin at week 12, both arms had "very good response rates, with 96 percent of subjects in the BIT225 arm having more than [a] two log reduction in virus levels, compared to 90 percent of the placebo arm".

The company said that virus levels might rebound in a proportion of patients receiving interferon and ribavirin once they stopped receiving treatment and the key time point for analysis of an antiviral effect for BIT225 was 12 weeks after completing all drug treatment, known as sustained virological response at Week 12 or SVR12 and patients with undetectable virus at this time were considered cured of hepatitis C infection.

The company said that the SVR12 point for the genotype 3 cohort was mid-August 2015 and for the genotype 1 cohort was February 2016.

Biotron said that preliminary analyses indicated that subjects in the BIT225 arms cleared virus from plasma faster than those in the placebo arm and supported findings from previous trials suggesting BIT225 in combination with other direct-acting antiviral drugs reduced treatment time.

The company said that the Committee noted that more patients than expected were failing treatment with the new direct-acting antiviral drugs and this population had very limited choices and might be an area of interest for BIT225.

Biotron fell 2.5 cents or 17.9 percent to 11.5 cents with 5.1 million shares traded.

SIMAVITA

Simavita says it has a confidential non-exclusive distribution agreement with Paul Hartmann for its smart incontinence management (SIM) system in Australia
Simavita said it would work with Hartmann to introduce SIM to new customers, targeting a minimum of 50 aged care facilities operated by Hartmann customers.
Simavita said the two companies would collaborate on commercial opportunities such as tenders within the residential aged care industry and engage in joint sales and marketing.
The company said that Hartmann had placed an initial undisclosed order of SIM products to stock its warehouses in preparation for despatch to customers.
Simavita said the agreement was the second of its kind to be executed with an Australian distribution partner and it would continue to sell and market SIM with its own sales force directly to Australian customers.
Simavita was up 1.5 cents or 2.75 percent to 56 cents.

PHYTOTECH MEDICAL

Phytotech says that on June 11, 2015 it filed documents to Israeli authorities for phase I and II trial of medical marijuana for multiple sclerosis.
Phytotech said the documents included the clinical study protocol and investigative brochure for trials of its oral tetrahyrocannabidiol (THC) and cannabidiol (CBD combination capsules to Israel's National Clinical Trial Committee and to an institutional review board for the trials, which were expected to begin by the end of 2015.
The company said that the submission of the documents was “a key milestone indicating advanced development stage and readiness to initiate [a] phase I clinical study” and was designed to fulfil the regulatory requirements for a new drug application to the US Food and Drug Administration.
Phytotech said that the phase I study, at the Tel Aviv, Israel-based Sourasky Medical Clinical Research Center, would be a single-centre, randomized, crossover study to compare the safety, tolerability and pharmacokinetics in healthy volunteers of the two oral formulations administered as single doses and the study objectives included the selection of the optimal THC and CBD formulations and was expected to conclude after nine weeks.
Phytotech said that following completion of the phase I study, the expected phase II study would assess the drug’s efficacy in multiple sclerosis patients, compared to the buccal-delivered Sativex, and would focus on the drug's capability to relieve pain and spasticity.
The company said the phase II trial was expected to begin in 2016 and be completed in 2017.
Phytotech was unchanged at 31 cents.

ANALYTICA

Analytica requested a trading halt and told the ASX that a planned capital raising and potential director appointment could explain recent trading in its securities.
The ASX said the company’s share price climbed 80.0 percent from one cent on June 23 to 1.8 cents on July 3, 2015, and noted an increase in trading volumes.
Analytica said it had engaged Patersons Securities “to advise it in relation to an equity capital raising and is in advanced preparations for the raising”.
The company said that if the raising was successful “a new director with extensive experience in commercialization of medical devices such as … [its] Pericoach product may join the board”.
Analytica last traded at 1.7 cents.

ORTHOCELL

Orthocell has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 15.15 percent from 33 cents on July 3 to 38 cents today, July 6, 2015, and noted an increase in trading volume.
Orthocell climbed 6.5 cents or 19.7 percent to 39.5 cents with 1.8 million shares traded.

BENITEC

RA Capital Management has reduced its substantial shareholding in Benitec from 11,629,031 shares (10.05%) to 10,429,325 (9.00%).
The Sydney-based RA Capital said the shares were held by RA Capital Healthcare Fund and Blackwell Partners, gave Citigroup as its address, and said the two entities sold 1,199,706 shares on-market for $991,563 or an average of 82.65 cents a share.
In February, RA Capital sold 1,175,047 shares on-market for $1,122,383 or an average of 95.5 cents a share (BD: Feb 19, 2015).
In 2014, RA Capital acquired 7,009,346 shares and then became a substantial holder in the $31.5 million placement at $1.07 a share (BD: Feb 24, Apr 17, 2014).
In a separate announcement, Benitec said the reduction was "a trimming of RA Capital's investment in Benitec".
Benitec fell two cents or 2.7 percent to 73 cents.

SUN BIOMEDICAL

SRV Custodians says it has become a substantial shareholder in Sun with 81,574,778 shares or 6.16 percent of the company.
The Perth, Western Australia -based SRV substantial shareholder notice, signed by director Matthew Callahan said that SRV as trustee for the SRV Tech Trust acquired the shares in consideration for 7,390,267 Dimerix shares.
Sun recently acquired Dimerix (BD: May 13; Jul 3, 2015)
Sun fell 0.1 cents or 9.1 percent to one cent with 1.45 million shares traded.

RHINOMED

Rhinomed says that the winner of the 2013 Tour de France bicycle race Chris Froome has been appointed its Turbine nasal plug "global ambassador".
Rhinomed said that Mr Froome had also won the Tour of Oman, the Tour de Romandie, came second in the Vuelta a Espana and a bronze medal at the 2012 Olympic Games.
The company said that Mr Froome wore the Turbine during the first stage of this year's Tour de France, which began in Utrecht, Netherlands and would conclude along the Champ de'Elysee in Paris on July 26, 2015.
Rhinomed chief executive officer Michael Johnson said that Mr Froome "provided extensive input and data into the new Turbine design and we are thrilled to have now locked in this long-term relationship".
The company said that Murdoch University in Western Australia was undertaking a confirmation trial on the new Turbine to gather data and confirm the impact of the Turbine breathing technology on performance and recovery.
Rhinomed was unchanged at three cents with 1.9 million shares traded.

USCOM

Uscom says it has appointed former Welch Allyn executive Stephen Wilson as US business development vice-president.

Uscom said that Mr Wilson was formerly the New York-based Welch Allyn's director of corporate development and would focus on driving US reimbursement, distribution, sales and marketing growth.

The company said that Mr Wilson had 10 years experience as a medical device executive for Welch Allyn in the US and Singapore.

Uscom said that Mr Wilson was an electrical engineer and held a Masters in Computer Engineering and a Masters in Business Administration from the University of Chicago Booth School of Business.

Uscom was up half a cent or 3.2 percent to 16 cents.