Biotech Daily

Thursday August 7, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: PHOSPHAGENICS UP 10%, BENITEC DOWN 5%**

*** US NIH FUNDS MESOBLAST END-STAGE HEART FAILURE TRIAL**

*** JAPAN APPROVES NANOSONICS TROPHON EPR**

*** PHARMAUST TREATS FIRST PPL-1 CANCER PATIENT**

*** BLUECHIIP, ST MICRO MOVE TO HIGH VOLUME TAG PRODUCTION**

*** CALZADA EXPECTS LOSS UP 67%, HUNTING KEY STAFF**

*** DAMIEN, JUSTIN HAAKMAN, DUSSMAN TAKE 43% OF SIMAVITA**

MARKET REPORT

The Australian stock market slipped 0.05 percent on Thursday August 7, 2014 with the S&P ASX 200 down three points to 5,509.0 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, five traded unchanged and eight were untraded.

Phosphagenics was the best, up 0.9 cents or 10.1 percent to 9.8 cents with 9.4 million shares traded.

Osprey climbed 6.4 percent; Avita rose five percent; Anteo and Biotron were up four percent or more; Antisense, Nanosonics and Tissue Therapies were up more than three percent; Alchemia, Prana and Prima rose more than two percent; Pharmaxis and Starpharma were up more than one percent; with Mesoblast and Resmed up by less than one percent.

Benitec led the falls, down five cents or 5.3 percent to 90 cents with 171,771 shares traded.

Bionomics lost 4.1 percent; Acrux, Analytica, Cochlear, Genetic Technologies and Patrys fell more than three percent; GI Dynamics, Neuren and Universal Biosensors shed two percent or more; Impedimed, Medical Developments and Viralytics lost more than one percent; with CSL and Sirtex down by less than one percent.

MESOBLAST

Mesoblast says the US National Institutes of Health will fund a 120-patient trial of a single injection of 150 million mesenchymal precursor cells for patients requiring heart pumps.
Mesoblast said the NIH's National Heart, Lung and Blood Institute would collaborate on the $15 million to $20 million trial, effectively a phase IIb/III study, of adult stem cells for patients with advanced heart failure requiring an implantable left ventricular assist device (LVAD) to maintain circulatory support.
The company said that the trial was a double-blind, placebo-controlled, two-to-one randomized design being conducted in more than 20 sites across the US.
Mesoblast said that the primary efficacy endpoint of the study was the number of temporary weans from LVAD tolerated over 12 months, with the study also evaluating patient survival and re-hospitalization over 12 months.
The company said that the 150 million cell dose selected for direct cardiac injection in the study was the same dose being evaluated in the ongoing phase III trial of about 1,700 patients with class II-III heart failure, sponsored by partner, Teva Pharmaceutical Industries and actively enrolling patients across multiple sites in the US.
Mesoblast said that the key objectives were to improve heart muscle function sufficiently to reduce the need for LVAD support and to reduce the long-term complications of LVAD implantation which resulted in recurrent hospitalizations.
The company said that the trial would be supported by the NIH National Institute of Neurological Disorders and Stroke and the Canadian Institutes for Health Research.
Mesoblast chief executive Prof Silviu Itescu said the trial of its stem cells in patients with the most advanced stage of heart failure was complementary to the ongoing phase III Teva program in patients with earlier stage disease.
The company said that the trial would be conducted by the NIH-funded Cardiothoracic Surgical Trials Network.
Mesoblast said the study built on the findings published in the June issue of the journal Circulation of a double-blind study in 30 patients which showed the potential benefits of a single intra-cardiac injection of 25 million mesenchymal precursor cells in advanced heart failure and LVAD implantation (BD: Jun 25, 2014).
Mesoblast said that the phase III Teva trial's primary efficacy endpoint was a time-to-first event analysis of heart failure-related major adverse cardiac events, defined as a composite of cardiac-related death or resuscitated cardiac death, or non-fatal decompensated heart failure events.
Mesoblast was up one cent or 0.25 percent to $4.02 with 668,368 shares traded.

NANOSONICS

Nanosonics says its Trophon EPR ultrasound probe cleaning system has been granted regulatory approval in Japan.
Nanosonics chief executive officer Michael Kavanagh said Japan was "an important market as part of our overall strategic growth agenda".
"It is a significant market globally from an ultrasound perspective and represents an important opportunity for our Trophon EPR technology," Mr Kavanagh said.
"The approval comes earlier than expected which is a credit to our regulatory team's efforts," Mr Kavanagh said.
"We are currently finalizing the Japanese product variant for introduction into manufacturing as well as our overall commercialization strategy and expect to enter the Japanese market in the second half of the 2015 financial year," Mr Kavanagh said.
Nanosonics was up 2.5 cents or 3.1 percent to 82 cents.

PHARMAUST

Pharmaust says it has begun treatment of its first of up to 15 patients in its open-label, phase I/II dose escalation trial of PPL-1 for cancer at the Royal Adelaide Hospital.
Pharmaust said that the patient had colorectal cancer with lung and liver metastases.
The company said the trial was led by Prof Michael Brown and managed by IDT's CMax contract research organization based at the Royal Adelaide Hospital with analytical services by the Adelaide-based CPR Pharma Services.
Pharmaust said that each patient would receive PPL-1 daily for 28 days and be given the option to continue on the drug passed the initial treatment period.
Pharmaust said that PPL-1 was an approved drug launched years by an animal health corporation for the treatment of parasitic diseases in animals.
The company said that its wholly-owned subsidiary, Pitney Pharmaceuticals owned patents on the use of PPL-1 in cancer and malignant disease.
Pharmaust said that University of New South Wales commercialization arm New South Innovations, it had received royalty-free assignments of the intellectual property relating to the use of PPL-1 in cancer from the University of New South Wales.
The company said that research into the mechanism of action of PPL-1 with Sydney's St George Hospital indicated that cancer inhibitory pathways were involved in the action of the molecule.
Pharmaust executive chairman Dr Roger Aston said that "as a first-in-man study, the drug will be potentially administered to patients suffering from diverse cancers".
"Recruitment will include selection of patients suffering from lung, pancreas, oesophageal, gastric, colorectal, ovarian, breast, prostate, liver, sarcoma, lymphoma and melanoma," Dr Aston said.
Pharmaust was up 0.1 cents or 10 percent to 1.1 cents with 4.8 million shares traded.

BLUECHIIP

Bluechiip says that the Geneva Switzerland-based ST Microelectronics will undertake high-volume production for more than one million tracking tags a year.
Bluechiip said that the micro-electro-mechanical system (MEMS) tracking tags had been jointly developed with ST Microelectronics and they were "an ultra-high-integrity, all-mechanical tracking chip that, unlike an electronic tag, is impervious to extreme high and low temperatures, gamma radiation, moisture, and other harsh conditions that would compromise traditional identification or tracking solutions such as labels, barcodes, or [radio-frequency identification] technologies".
The company said the new chip used MEMS resonator technology and contained no electronics, with each chip individually pre-programmed during manufacture with a unique identification, a process that makes it tamper proof, as well.
Bluechiip chief executive officer Dr Jason Chaffey said that ST was "a valued partner ... and has played a key role in facilitating the Bluechiip tag to be adopted in more universal applications".
Bluechiip said its tracking tag had been adopted by customers in Australia, China, Italy, and the US, mainly in bio-banking and other biomedical related fields such as pathology, clinical trials, and bio-repositories.
Bluechiip said that although the tracking technology was developed for the healthcare and biomedical industries, its robustness, ability to track temperature and resistance to tampering was suited for other high-value applications in food, vaccines, security, defense, aerospace, and aviation.
Bluechiip was up 0.1 cents or 1.5 percent to 6.9 cents with 2.1 million shares traded.

CALZADA

Calzada says it expects to post a net loss after tax of about $2.5 million for the year to June, 30 June 2014, a 66.7 percent increase from the prior year's $1.5 million loss.
Calzada said the increased loss was mainly attributable to the payment in 2012-'13 of the Federal Government's Research and Development Tax Incentive for the two years to june 30, 2013, whereas this year the company had a single year's Tax Incentive.
The company said that expenditure in the year to June 30, 2014 was about $330,000 higher than in the previous corresponding period.
Calzada said that the increased expenditure was primarily associated with regulatory costs in respect to the US Food and Drug Administration and Conformité Européenne (CE) mark submissions for its Novopore biodegradable temporizing matrix wound treatment, as well as the cost of national phase filings for the new AOD9604 patents including joint disease, and muscle and cartilage repair, and costs associated with a $3.85m capital raising in 2013.
The company said it was in the process of recruiting a managing director and several other senior appointments.
Calzada fell half a cent or four percent to 12 cents.

SIMAVITA

Simavita says that Dussman Pty Ltd and directors Damien and Justin Haakman have increased their holding to 31,493,464 shares and Chess depositary interests (42.72%).
In a complicated and confusing Canadian regulatory filing, the Narre Warren South, Melbourne-based Dussman said it was acting as the trustee for Devonia Investment Trust, the Charolais Super Fund No 2 and the Charolais Super Fund No 3.
Dussman said that it acquired 6,168,880 Chess depositary interests at 45 cents a share in the recent placement (BD: Jun 19, 23, 2014).
The regulatory filing did not say that Damien Haakman was a non-executive director of Simavita, which was disclosed in a separate, previous ASX Appendix 3Y Change of Director's Interest Notice.
Both the ASX and the Corporations Act provide exemptions from certain filings for specified off-shore domicile companies and Simavita is a Canadian company, despite being listed on the ASX and being based in Sydney.
Simavita fell one cent or 2.2 percent to 45 cents.