Biotech Daily

Thursday July 7, 2011

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: CATHRX UP 15%; IMPEDIMED DOWN 4%**

*** FDA CLEARS MESOBLAST, CEPHALON PHASE III BONE MARROW TRIAL**

*** AGENIX REPORTS PHASE II THROMBOVIEW ACCURACY, SAFETY**

*** RESMED ACQUIRES DUBLIN'S BIANCAMED FOR MORE THAN $15m**

*** BIOTRON DOSES LAST PHASE IIa BIT225 HEPATITIS C PATIENT**

*** CELLESTIS EXPECTS REVENUE UP 22% TO $50m; PROFIT EVEN AT $8m**

*** GE RAISES NANOSONICS ORDER TO $2.4m**

*** AUSTRALIAN ETHICAL REDUCES TO 6.2% OF ATCOR**

MARKET REPORT

The Australian stock market was flat on Thursday July 7, 2011 with the S&P ASX 200 up half a point to 4605.5 points.

Fifteen of the Biotech Daily Top 40 stocks were up, seven fell, 10 traded unchanged and eight were untraded.

Cathrx was best, up two cents or 15.4 percent to 15 cents with 6,900 shares traded, followed by Prima up 10.3 percent to 32 cents with 17.7 million shares traded.

Phylogica climbed 8.2 percent; Living Cell and Optiscan were up more than six percent; Universal Biosensors and Virax were up four percent or more; Phosphagenics, Psivida and Starpharma were up more than three percent; Patrys rose 2.15 percent; with CSL and Mesoblast up more than one percent.

Impedimed led the falls, down 2.5 cents or 4.3 percent to 55.5 cents with 39,899 shares traded, followed by Cellmid down 4.2 percent to 2.3 cents with 871,311 shares traded.

Tissue Therapies lost 3.3 percent; with Cellestis, Clinuvel and Resmed down more than one percent.

MESOBLAST

Mesoblast says the US Food and Drug Administration has approved a 240-patient phase III clinical trial for bone marrow regeneration in patients with blood cancers.

Mesoblast said the trial would “aim to reproduce the positive pilot trial results” at the University of Texas MD Anderson Cancer, where accelerated neutrophil and platelet recoveries, excellent 100-day patient survival and low graft versus host disease rates, occurred in patients receiving partially mismatched haematopoietic cells from umbilical cord blood expanded by its mesenchymal precursor cells.

Mesoblast said the trial, at 50 centers in the US, Europe and Australia, would enroll 240 patients with haematologic malignancies undergoing unrelated donor bone marrow transplantation using matched or partially mismatched umbilical cord blood.

The company said that patients would be randomized to receive either non-expanded cord blood or cord blood expanded by Mesoblast’s mesenchymal precursor cells and containing 40-fold higher numbers of haematopoietic cells.

Mesoblast said that the primary endpoint was a shortened time to neutrophil and platelet recovery in the treatment group.

Mesoblast chief executive Prof Silviu Itescu said the initiation of a phase III trial was a “landmark milestone”.

“This achievement again underscores the strength and robustness of Mesoblast’s clinical, regulatory and manufacturing capabilities,” Prof Itescu said.

“We hope that this particular product will make bone marrow transplantation a more widely used and safer option for critically ill patients who undergo chemotherapy to potentially cure blood cancer … and has the potential to be the first of our revenue generating biologic therapies in both the United States and Europe,” Prof Itescu said.

Mesoblast said its strategic partner Cephalon would fund the trial.

The company said its off-the-shelf mesenchymal precursor cells were being developed under an orphan drug designation for the condition of insufficient haematopoietic stem cell production in patients with haematologic malignancies who had failed treatment with conventional chemotherapy.

Mesoblast said those patients were in need of bone marrow transplants using either their own (autologous) or unrelated donor (allogeneic) haematopoietic stem cells.

Mesoblast said its stem cells potentially could be used to expand both autologous and allogeneic hematopoietic stem cells and its cells expanded haematopoietic precursor cells in umbilical cord blood 40-fold, enabling rapid bone marrow reconstitution with lowered risk of life-threatening graft versus host disease.

The company said more than 60,000 autologous and allogeneic bone marrow transplants were performed each year of which about 25,000 transplants were allogeneic, but less than 30 percent of individuals received an unrelated donor bone marrow transplant because fully matched donors could not be found.

Perfect matching is required for adult marrow transplants because of the very high risk of potentially life-threatening graft versus host disease when unmatched transplants were performed, the company said.

Mesoblast said that cord blood caused significantly less graft versus host disease and could be used as a partially mismatched donor source, but the number of haematopoietic precursor cells in unexpanded cord blood was too few to enable sufficiently robust and predictable bone marrow engraftment.

Mesoblast said its objective was to make available a source of unrelated donor haematopoietic precursor cells from cord blood which could be used without full matching.

Mesoblast was up 12 cents or 1.4 percent to $8.58.

AGENIX

Agenix says that a phase II study shows Thromboview's sensitivity and specificity for acute pulmonary embolism is comparable to contrast-enhanced computed tomography.

Agenix said the 52-patient, multi-centre phase II study, led by University of California San Diego Medical Center Dr Timothy Morris was intended to evaluate the efficacy and accuracy Thromboview in patients with suspected acute pulmonary embolism.

The company said the study found Thromboview was well-tolerated by patients and enhanced the ability to accurately diagnose acute pulmonary embolism.

The results have been published in an article entitled 'SPECT Imaging of Pulmonary Emboli with Radiolabeled Thrombus-Specific Imaging Agents' published by the American Journal of Respiratory and Critical Care Medicine.

An abstract is at http://www.ncbi.nlm.nih.gov/pubmed/21680946.

Agenix said that all patients in the study conducted at six hospitals in Canada and the US were being evaluated for suspected acute pulmonary embolism and the sensitivity and specificity of Thromboview for acute pulmonary embolism was comparable to what had been previously reported for contrast-enhanced computed tomography (CT) scanning.

The company said the the researchers reported no adverse events and concluded that Thromboview was accurate, safe and well-tolerated in patients with a range of co-existing diseases in the chest and elsewhere.

"There is a large unmet medical need worldwide for an accurate test that can detect blood clots throughout the body without exposing patients to toxic contrast agents and the high radiation dose to the chest associated with a CT scan," Dr Morris said.

Agenix said that venous thromboembolism or a blood clot in a vein was a disease that included deep vein thrombosis and pulmonary embolism, with 600,000 clinically recognized incidences of venous thromboembolism in the US each year.

The company said pulmonary embolism was the third most common cardiovascular illness after acute coronary syndrome and stroke and the third most common cause of hospital-related death and the most common preventable hospital-related death due to a failure by available medical technology to accurately diagnose the problem.

Agenix said the current standard for diagnosing pulmonary embolism was computed tomography pulmonary angiography, which delivered a substantial radiation dose to the chest and involved the injection of a contrast agent through the patient's leg or arm, followed by a computerized axial tomography scanner taking a series of images of the lungs from different angles.

Agenix said its Thromboview offered a more accurate test without exposing patients to contrast agents that can be highly toxic to the kidneys, nor to the high radiation dosages to the chest associated with computed tomography pulmonary angiography.

The company said Thromboview only required only a standard hospital gamma camera to take a single photon emission tomography (SPECT) image from which the reader could easily identify the presence, absence and location of a blood clot.

Agenix said Thromboview has completed two US Food and Drug Administration phase II human clinical trials and the company had "revitalized its partnering program" for the technology.

The company said it was working to partner with a medical and pharmaceutical company for the final clinical phase for Thromboview's US and European regulatory approval and was "working to create access-to-technology and royalty revenue streams which will extend beyond expiry of its patents in 2022, namely 12 years from the date of regulatory approval for biologics in the US and 10 years in Europe".

Agenix was up 0.3 cents or 21.4 percent to 1.7 cents.

RESMED

Resmed says it has acquired the Dublin-based Biancamed medical technology company for significantly more than $14.7 million.

A Resmed executive told Biotech Daily that the amount paid was undisclosed but it was “a significant premium above the EUR11 million” ($A14.7 million) the company was valued and noted that Biancamed was considered a small start-up company.

The executive said that Resmed already owned 13 percent of Biancamed and in a media release Resmed said it had purchased all the outstanding shares with cash.

Resmed said Biancamed had developed and was marketing “an innovative, convenient, non-contact device to monitor sleep and breathing in the home and hospital”.

The company said Biancamed’s Sleepminder was an accurate, touch-free device that measured sleep and breathing with sophisticated biometric software.

Resmed said the core of Biancamed’s proprietary technology was a motion sensor that could detect respiration and movement without physical contact with the human body.

The company said Biancamed was developing a number of other applications for the technology, across a range of medical and consumer settings.

Resmed said that Biancamed would become part of its ventures and initiatives unit and it would retain Biancamed’s 29 employees and the office in Dublin will remain active.

Resmed said the acquisition would dilute its earnings per share by about four US cents in the 2011-‘12, excluding amortization of intangibles and one-time acquisition related costs.

Resmed chairman and chief executive officer Dr Peter Farrell said his company was “committed to innovation in sleep and respiratory medicine and the related co-morbidities by commercializing products incorporating novel technologies”.

“We have worked closely with Biancamed for many years and have been investors since their inception in 2003,” Dr Farrell said.

“We believe there are many opportunities for Biancamed’s applications that will provide future growth and we look forward to maintaining and building the Biancamed team,” Dr Farrell said.

Resmed fell three cents or one percent to $2.86 with 2.6 million shares traded.

BIOTRON

Biotron says it has begun dosing the final patient in its phase IIa trial of BIT225 in combination with Interferon and Ribavirin for chronic hepatitis C infection

Biotron said it expected to have the results by September 2011.

The company said 24 patients infected with the most common strain of the Hepatitis C virus, genotype 1, were enrolled in the study at an international trial site in Bangkok, Thailand.

Biotron said patients in the double-blinded, randomized trial received BIT225 for 28 days, with eight patients receiving either 400mg BIT225, 200mg BIT225 or placebo.

The company said that BIT225 was a first-in-class drug candidate which specifically targeted the p7 protein, a viral protein essential to virus production and replication.

Biotron managing director Dr Michelle Miller said the dosing of the last patient was “a significant milestone”.

Biotron was up 0.7 cents or 7.1 percent to 10.5 cents.

CELLESTIS

Cellestis says it expects revenue for the 12 months to June 30, 2011 be about $50 million a 21.6 percent increase over the previous year's $41.11 million.
Cellestis said it expected to post a net profit after tax excluding takeover scheme costs for the 12 months to June 30, 2011 of $9.3 million a 12.7 percent increase over the previous year.
The company said scheme costs were about $1.3 million and the resultant net profit after tax would be more than $8 million.
Cellestis is the subject of a takeover bid from Qiagen NV at $3.55 a share, which is opposed by a group of shareholders claiming to hold enough shares to block the bid at a scheme meeting (BD: Apr 14, 2011).
Cellestis said the revenue and profit figures were subject to validation and audit clearance.
Cellestis fell five cents or 1.6 percent to $3.13.

NANOSONICS

Nanosonics says GE Healthcare has begun its US launch of the Trophon EPR and upgraded its initial order to more than $2.4 million.
Nanosonics said the order included the ultrasound probe disinfection system as well as the chemical indicator and Sonex-HL disinfectant cartridges.
The company said the US order would be shipped progressively with the first delivery received by GE at the end of June.
Nanosonics said that in consultation with GE Healthcare it believed that the overall market opportunity exceeded initial expectations.
The company said the commercial potential was reinforced by the approval of Trophon EPR for use with transducers by key ultrasound manufacturers including GE, Siemens and Phillips and these approvals covered a large share of the ultrasound probes sold worldwide.
Nanosonics said it had implemented early production capability of the US version of the Trophon EPR.
Nanosonics was up half a cent or 0.6 percent to 82 cents.

ATCOR MEDICAL

Australian Ethical Smaller Companies Trust has decreased its substantial shareholding in Atcor from 9,955,193 shares (7.42%) to 8,272,193 shares (6.17%).
Australian Ethical said the 1,683,000 shares were sold for $236,833 or an average price of 14.07 cents a share.
In March, Australian Ethical bought 1,359,291 shares for $135,608 or 10 cents a share (BD: Mar 8, 2011).
Atcor was untraded at 14 cents.