# Biotech Daily

Tuesday May 24, 2011

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: BENITEC UP 15%; OPTISCAN DOWN 17%**

*** RESMED REORGANIZES MANAGEMENT FOR NEW INDICATIONS**

*** CANCER TRIALS AUSTRALIA CLOSES TRIAL, TRANSLATIONAL LAB**

*** GERMANY, BRAZIL APPROVE REVA REZOLVE STENT TRIAL**

*** CEPHALON SLOWLY INCREASES TO 84% OF CHEMGENEX**

*** US DENTAL PULP FAT COMPOSITION PATENTS FOR MESOBLAST**

*** AUSTRALIAN METHODS PATENT FOR CLINUVEL'S SCENESSE**

*** IMMURON APPOINTS DR ARUN SANYAL FOR IMM-124E PHASE IIb TRIAL**

*** FULLERTON TAKES 8% OF OMI**

## MARKET REPORT

The Australian stock market fell 0.31 percent on Tuesday May 24, 2011 with the S&P ASX 200 down 14.2 points to 4628.8 points.

Eight of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and six were untraded.

Benitec was best, up 0.4 cents or 15.4 percent to three cents with 24.1 million shares traded, followed by Prana up 14.7 percent to 19.5 cents with 65,800 shares traded and Antisense up 10 percent to 1.1 cents with 1.6 million shares traded.

LBT climbed 7.1 percent; Viralytics was up 6.8 percent; with QRX up 2.1 percent.

Optiscan led the falls, down 0.9 cents or 17.3 percent to 4.3 cents with 151,000 shares traded, followed by Genetic Technologies down 8.2 percent to 22.5 cents with 1.2 million shares traded.

Cathrx lost 7.5 percent; Cellmid, Circadian, Phosphagenics, Sunshine Heart and Virax fell more than three percent; Acrux, Alchemia, Compumedics, Impedimed, Nanosonics and Sirtex shed more than two percent; with Biota, Mesoblast, Starpharma and Universal Biosensors down more than one percent.

RESMED

Resmed has reorganized its management, expanding its indications, following the departure of chief executive officer Kieran Gallahue earlier this year (BD: Feb 2, 2011)

Resmed chairman and chief executive officer Dr Peter Farrell said the company was "dedicated to providing innovative solutions that meet the needs of our sleep disordered breathing patients and our distributors".

"We are also passionate about addressing the widespread ignorance which exists concerning the strong correlation between untreated [sleep disordered breathing] and such co-morbidities as cardiac disease, metabolic syndrome, type 2 diabetes, chronic obstructive pulmonary disease, peri-operative risk and occupational health and safety," Dr Farrell said.

Dr Farrell said Resmed had clinical data the showed that treating sleep disordered breathing (SDB) with nasal continuous positive airways pressure (CPAP) ameliorated and, in some cases, reversed the complications associated with these disease states, when SDB was present.

"We have elected to reorganize certain business units and management responsibilities to more effectively align our activities with our strategic goals," Dr Farrell said.

Resmed said the structure combined three business units into two, created a strategic business unit and confirmed other roles in the commercial, manufacturing, logistics, supply and corporate staff areas.

The company said the former head of the patient interface strategic business unit Don Darkin would lead the combination of the former sleep and patient interface organizations as president of the SDB strategic business unit, responsible for product development, product marketing and related activities that address sleep disordered breathing.

Resmed said the form head of the ventilation strategic business unit Geoff Neilson would become president of the new respiratory care strategic business unit, with a focus on chronic obstructive pulmonary disease and be responsible for product development, product marketing, and related activities.

The company said a new strategic business unit, Resmed Ventures and Initiatives, would focus on opportunities in disease states related to treating sleep disordered breathing and other market opportunities and be led by Jean-Claude Kyrillos.

Resmed Ventures and Initiatives will focus on sleep disordered breathing diagnostic and treatment opportunities in patients with concomitant cardiac disease and metabolic syndrome type 2 diabetes and would focus on treating sleep disordered breathing in the perioperative care environment and in the use of dental appliances to treat mild to moderate SDB.

Resmed said it would continue to operate through three geographic commercial regions with Robert Douglas head of Asia Pacific and chief, global supply operations,Stein Jacobsen head of European sales and commercial activities and Michael Farrell head of American sales and commercial activities.

Resmed said Brett Sandercock would continues as chief financial officer responsible for finance, accounting, and investment activities, with Michael Zill as chief information officer and David Pendarvis chief administrative officer and global general counsel responsible for legal, human resources, training and development, and investor relations.

The company said Jim Hollingshead would be the chief strategy officer responsible for corporate strategy and business development and will collaborate closely with Resmed Ventures and Initiatives group.

Resmed was unchanged at $2.94 with 5.25 million shares traded.

## CANCER TRIALS AUSTRALIA

Cancer Trials Australia will close the operations of its clinical trial and translational laboratory.

Cancer Trials Australia chief executive officer Marcus Clark said in a media release that it was “a very sad moment for the group as the laboratory has been in existence since 2005 and assisted many Australian biotech companies with the development of their first assays for clinical trials”.

“Unfortunately it has struggled financially due to trends by [pharmaceutical] groups to centralize much target assay work,” Mr Clark said.

“Engagement with such groups is pivotal to the sustainability of such an operation and we haven't been successful in gaining such business,” Mr Clark said.

“We are in the process of assigning contracts to other laboratories and this has been assisted by the invaluable help of Melbourne Health Pathology who have been our landlord as well as collaborator on many projects,” Mr Clark said.

“Melbourne Health is a founding member of CTA and our needs for laboratory services will often be provided via this strong relationship,” Mr Clark said.

The organization said it had been a clinical trial network and site service organization providing research governance, advisory and laboratory assay services to investigators and sponsors of clinical trials in the field of oncology.

## REVA MEDICAL

Reva says it has approval from the German health authority Bfarm and the Brazilian Ministry of Health to begin its clinical trial of the Rezolve bio-resorbable coronary stent.

Reva said the trial would evaluate the safety of of the Rezolve stent, which was designed to restore blood flow and promote arterial healing, then gradually dissolve, leaving nothing behind.

The company said the trial would initially enroll patients in multiple centers in Brazil and Germany and was expected to begin by October 2011.

Reva chief executive officer  Robert Stockman said the approvals were a “very important regulatory milestone”.

The company said the Rezolve stent was designed to offer full x-ray visibility, clinically relevant sizing and a controlled and safe resorption rate.

Reva said that by early encapsulation of the stent in the artery tissue coupled with the loss of stent structure over time, the Rezolve stent could reduce the incidence of late forming blood clots, or thromboses, a rare but serious problem associated with drug-eluting metal stents currently on the market.

Reva was up five cents or 4.8 percent to $1.10.

## CHEMGENEX

Cephalon says it has increased acceptances for its Chemgenex takeover bid from 259,363,150 shares (82.72%) to 263,297,471 shares (83.97%).

Cephalon said it had increased Chemgenex listed options acceptances from 9,463,604 options (86.43%) to 9,480,417 options (86.58%).

The bid is conditional on receiving 90 percent of shares and options.

Cephalon can remove conditions at any time.

Chemgenex was unchanged at 69.5 cents.

## MESOBLAST

Mesoblast says two US composition of matter patents have “significantly strengthened” its product development strategy.

Mesoblast said the composition of matter claims granted by the US Patent and Trade Mark Office was for two distinct patent families to which it had exclusive worldwide commercial rights.

The company said the new patents entitled ‘Adult human dental pulp stem cells in vitro and in vivo’ (US patent 7,052,907) and ‘Perivascular mesenchymal precursor cells’ (US patent 7,947,266) gave exclusive ownership over mesenchymal precursor cells derived from a variety of sources, including dental pulp and adipose tissue or fat, in addition to bone marrow.

Mesoblast said the mesenchymal precursor cells derived from dental pulp may be particularly effective for the treatment and prevention of neural degenerative diseases such as Parkinson's disease and Alzheimer’s disease, as well as for dental applications such as regenerating teeth.

The company said that Adipose-derived mesenchymal precursor cells could have particular benefits for reconstructive surgery and cosmetic indications.

Mesoblast said the US patents extended its ownership of mesenchymal precursor cells to 2025 and ensured that only Mesoblast could commercialize mesenchymal precursor cells products in the US.

The company said that beyond 2025, under the US Patient Protection and Affordable Care Act (commonly called Obamacare) enacted in 2010, Mesoblast may be entitled to further exclusive commercial protection for its biologic products in the US.

Mesoblast chief executive Prof Silviu Itescu said the new patents were major assets that gave certainty, broadened the range of product offerings by the company and significantly increased the commercial value of the platform technology.

“Maintaining commercial exclusivity for our adult stem cell products through a robust international patent portfolio is fundamental to our commercial strategy,” Prof Itescu said.

Mesoblast fell 13 cents or 1.5 percent to $8.50 with 1.3 million shares traded.

## CLINUVEL PHARMACEUTICALS

Clinuvel says it has been granted an Australian patent for the use and manufacture of formulations of alpha melanocyte stimulating hormone (alpha-MSH) analogues.

Clinuvel said that IP Australia (formerly the Australian Patent Office) provided protection for the patent entitled ‘Methods of inducing melanogenesis in a subject’ until 2025.

The company said its lead drug Scenesse was a controlled-release injectable implant formulation of afamelanotide, an alpha-MSH analogue, which activated melanin in skin through melanogenesis, protecting it from ultraviolet and visible light.

Clinuvel said the patent covered the use of alpha-MSH analogue formulations to induce melanogenesis and prevent ultraviolet radiation-induced damage in humans, as well as the manufacture of medicaments and the use of pharmaceutical compositions containing alpha-MSH analogues for these purposes.

The company said clinical trials had shown that Scenesse provided photo-protection through increased melanogenesis in fair-skinned patients diagnosed with ultraviolet and light related skin disorders.

Clinuvel chief executive officer Dr Philippe Wolgen said the patent “provides additional evidence that Clinuvel will be able to capitalize on its investment in an increasingly competitive global pharmaceutical market”.

Clinuvel was unchanged at $1.80.

## IMMURON

Immuron says it has appointed Dr Arun J Sanyal as principal investigator for its phase IIb clinical trial of IMM-124E for non-alcoholic steato-hepatitis (NASH).

The company said Dr Sanyal was a professor of medicine and chairman of the Division of Gastroenterology at Virginia Commonwealth University Center in Richmond Virginia.

The company said Prof Sanyal was the immediate past president of the American Association for Study of Liver Diseases and a member of the American College of Gastroenterology and author of more than 80 articles in publications including, Gastroenterology, Hepatology and Journal of Infectious Diseases.

Immuron chief executive officer Joe Baini said Prof Sanyal would “add immense value to this important program”

“Immuron’s NASH product candidate is of particular interest to me based on the results achieved to date,” Prof Sanyal said.

“This drug candidate has shown promise to systemically address NASH,” Prof Sanyal said.

Immuron said that non-alcoholic steato-hepatitis, or fatty liver disease, was becoming increasingly prevalent in developed nations and was linked to increases in obesity rates and type 2 diabetes, with about 10 per cent of Americans aged 40 to 60 years affected, with the incidence seemingly more prevalent in women.

The company said IMM-124E was an orally administered drug candidate developed from it bovine colostrum drug technology platform.

Immuron said the previous phase IIa clinical trials of IMM-124E demonstrated its safety and efficacy against NASH, by clinically improving liver enzyme markers and key type 2 diabetes markers.

The company said early results also showed IMM-124E was able to decrease blood triglyceride levels and improve key pathways linked to chronic inflammation.

Immuron was untraded at 6.2 cents.

## OMI HOLDINGS

Fullerton Private Capital has become a substantial shareholder in OMI with the acquisition of 40,000,000 shares or 8.046 percent.

The initial substantial shareholder notice said that Fullerton acquired the shares for $220,000 or an average price of 0.55 cents a share.

The substantial shareholder notice said Fullerton was based in South Perth Westren Australia and was signed by director Evan Cross an executive director of Greenday Corporate.

OMI was unchanged at 0.6 cents with 6.6 million shares traded.