Biotech Daily

Monday August 6, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ANTISENSE UP 13%, ALLIED HEALTH DOWN 14%**

*** PROF ARUN SANYAL NIH GRANT COVERS IMMURON IMM-124E TRIAL**

*** FDA CONDITIONAL APPROVAL FOR SUNSHINE HEART'S NEW DRIVER**

*** CBIO STARTS CPN10 (XTOLL) FDA PROCESS FOR LUPUS**

*** MEDICAL DEVELOPMENTS DOSES FINAL PENTHROX EURO PATIENT**

*** CAPITAL INVESTMENT TRANSFERS 7% OF ATCOR**

*** CELLMID APPOINTS ANDREW BALD JOINT COMPANY SECRETARY**

MARKET REPORT

The Australian stock market rebounded 1.21 percent on Monday August 6, 2012 with the S&P ASX 200 up 51.1 points to 4,272.6 points.

Ten of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and 11 were untraded. All three Big Caps were up.

Antisense was the best, up 0.2 cents or 13.3 percent to 1.7 cents with 4.6 million shares traded, followed by Living Cell up 12.2 percent to 5.5 cents with 245,454 shares traded.

Cellmid and Sirtex climbed more than six percent; Anteo and Prima were up more than four percent; Phosphagenics and Resmed were up more than three percent; Cochlear rose 2.55 percent; with Acrux, Mesoblast and Pharmaxis up more than one percent.

Allied Health led the falls, down 0.3 cents or 14.3 percent to 1.8 cents with 248,000 shares traded.

Patrys lost 4.8 percent; Avita, Bionomics and Viralytics fell more than three percent; Circadian and Tissue Therapies shed more than two percent; with Nanosonics, Optiscan and Reva down more than one percent.

IMMURON

Immuron says the US National Institutes of Health has awarded Prof Arun Sanyal a grant to conduct a phase IIa clinical trial for alcoholic steato-hepatitis.

Immuron chief executive officer Joe Baini told Biotech Daily that the grant was for a program for alcoholic steato-hepatitis but included about $750,000 for the phase IIa trial.

Immuron said the Prof Santal was its principal investigator for an impending non-alcoholic steato-hepatitis phase IIb clinical trial and the two conditions were related.

The company said that based on its approach to treating non-alcoholic steato-hepatitis patients with its hyper-immune cow colostrum therapeutic IMM-124E, and following its phase I/IIa clinical trial in 2010 at the Hadassah Medical Center in Jerusalem by Prof Yaron Ilan, Prof Sanyal intended to trial IMM-124E on alcoholic steato-hepatitis patients.

The 10-patient Jerusalem trial showed efficacy for non-alcoholic steato-hepatitis and aspects of metabolic syndrome (BD: Aug 23, 2010).

Today Immuron said that a consortium of the Virginia Commonwealth University, Mayo Clinic and Indiana University would perform the trial over a 30-day dosing regimen.

The company said that alcoholic and non-alcoholic steato-hepatitis were characterized by fatty deposits on the liver, inflammation and a resulting deterioration of the liver.

Immuron said it expected the alcoholic steato-hepatitis study would provide further validation of the results generated from its 2010 phase I/IIa clinical trial.

Prof Sanyal said he was “excited to commence these trials for the treatment of a serious and under-treated medical condition”.

“Based on Immuron’s results to date, I expect to demonstrate that its hyperimmune colostrum based therapeutic will be able to deliver benefits to patients with [alcoholic steato-hepatitis] and provide an improvement in their condition,” Prof Sanyal said.

Immuron said that Prof Sanyal was a past president of the American Association for the Study of Liver Diseases.

Immuron was unchanged at 1.6 cents.

SUNSHINE HEART

Sunshine Heart says it has conditional approval from the US Food and Drug Administration for its next generation C-Pulse aorta cuff pump driver.

Sunshine Heart said the new driver was a single unit, lighter, quieter, about half the size of its predecessor, with software enhancements. designed to provide moderate to severe heart failure patients with greater comfort and performance.

The company said that FDA conditional approval allowed it to use the driver for investigational purposes in the US at all sites enrolled in its North American feasibility trial and it planned to provide the driver to all patients currently on its C-Pulse device at all US sites upon institutional review board approval.

Sunshine Heart said the driver was also expected to be used in the planned pivotal trial once the FDA has approved the investigational device exemption, as well as in Europe.

The company said that Health Canada approved the driver in its Canadian study at Royal Victoria Hospital in Barrie, Ontario (BD: Jun 8, 2012).

Today, Sunshine Heart said that Health Canada had approved an expansion of the number of participants in the trial to 20 patients and all new patients in the trial and future trials would receive the next generation C-Pulse driver.

Sunshine Heart was unchanged at 4.1 cents.

CBIO

CBio says it has requested a US Food and Drug Administration pre-investigational new drug application meeting for the development of Cpn10 for systemic lupus erythematosus.
CBio listed on the ASX to complete a phase II trial of chaperonin 10 (Cpn 10), then known as XToll, but the drug did not meet its endpoints (BD: Oct 9, 2009; Feb 8, 11, 2010; Aug 1, 2011).
Today, the company said a "type B" meeting request had been made and a face-to-face meeting was expected by the end of 2012.
CBio said it would offer its suggested pathway for the development of (chaperonin 10) in lupus and expected that prior to the meeting the FDA would request clinical, chemistry and toxicology information.
CBio said it would submit the investigational new drug application when all questions had been resolved, including an FDA-approved clinical trial protocol.
CBio chairman Dr Ralph Craven said the request was the first step in the new clinical development plan for Cpn10.
"The board's review of Cpn10 supports the drug's continued investigation, and lupus was identified as the most promising development target in terms of clinical need, regulatory path and competitive landscape," Dr Craven said.
"We are focused on this strategy and the further development of Cpn10 as one of the assets of the company following the merger with Inverseon Inc," he said.
CBio intends to merge with the US-based Inverseon to create a clinical-stage company that targets new anti-inflammatory treatments for a range of diseases including asthma, chronic bronchitis, cystic fibrosis and lupus, and be renamed Invion (BD: Jul 2, 2012).
CBio was untraded at 5.3 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has enrolled the 300th and final patient in its European phase III trial.
The company said the trial began in August of 2011 and was completed on time and on budget.
Medical Developments said the phase III trial was a randomized, double-blind, multi-centre, placebo-controlled study to evaluate the safety and efficacy of the Penthrox inhaler and its active ingredient methoxyflurane for the treatment of acute pain in patients presenting to emergency departments with minor trauma.
Medical Developments chief executive officer John Sharman said that data from the trial would be used to support an application for marketing approval in selected European countries.
Mr Sharman said he expected to finalize the European application by October 2013 and if the application was successful "the opportunity to sell Penthrox in Europe is significant".
Medical Developments chairman David Williams said that Penthrox had received registration in 10 countries and orders were building from a zero base.
"This is the first time the company will have world class European clinical data to support its registration and use in Western European markets," Mr William said.
Mr Sharman gave credit to Australian ambulance officers who had supported the product and could "take credit for Penthrox now being used in 10 other countries and for the trial that has taken place in the accident and emergency departments of six UK hospitals and the prospects that holds".
Medical Developments was up two cents or 2.15 percent to 95 cents.

ATCOR MEDICAL

Capital Investment Group has transferred part of its substantial shareholder in Atcor of 22,332,347 shares or 15.11 percent, in two tranches.

The initial substantial shareholder notice said that on August 2, 2012, Capital Investment acting for the Curran Superannuation Fund, which was associated with Capital Investment director Charles Paul Curran, acquired 10,000,000 shares (6.77%) for $650,000 or 6.5 cents a share, the share price on that day.

A Capital Investment executive told Biotech Daily that the company retained the balance of 12,332,347 shares or 8.34 percent.

Atcor fell half a cent or 7.7 percent to six cents.

CELLMID

Cellmid says it has appointed Andrew Bald as joint company secretary, working with Nicholas Falzon, effective from today.

Cellmid said Mr Bald had 25 years' experience in banking and corporate finance and had advised private and ASX-listed companies in a number of industries.

The company said that prior to his role as a corporate advisor, Mr Bald was an investment banker managing balance sheet and trading risks as well as advising on project financing transactions.

Cellmid was up 0.1 cents or 6.25 percent to 1.7 cents with 4.4 million shares traded.