Biotech Daily

Thursday March 4, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: OPTISCAN UP 26%; USCOM DOWN 14%**

*** PSIVIDA'S ILUVIEN EFFICACY FOR DME, WITH SOME SAFETY CONCERNS**

*** BIOMD PAEDIATRIC HEART PATCH TRIAL 'CONFIRMS POTENTIAL'**

*** EASTLAND COMPLETES PAEDIATRIC MALARIA DOSING**

*** BIOTA COMPLETES MAXTHERA ACQUISITION**

*** BANGS STARTS PRODUCTION WITH ANTEO'S MIX&GO**

*** STIRLING APPOINTS PROF GLYN TONGE DIRECTOR**

MARKET REPORT

The Australian stock market climbed 0.31 percent on Thursday March 4, 2010 with the S&P ASX 200 up 14.8 points to 4750.5 points.

Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and five were untraded.

Optiscan was best, up 1.8 cents or 25.7 percent to 8.8 cents with 266,922 shares traded, followed by Psivida up 24 cents or 6.9 percent to $3.70 with 1,862 shares traded.

Compumedics and Patrys climbed more than six percent; Phylogica was up 4.6 percent; Cathrx was up 3.85 percent; with Cellestis up 1.3 percent.

Uscom led the falls, down nine cents or 14.1 percent to 55 cents with 55,000 shares traded, followed by Tissue Therapies down 7.1 percent to 19.5 cents with 1.7 million shares traded.

Cellmid lost 6.1 percent; Clinuvel and Living Cell fell more than five percent; Antisense, Phosphagenics, and Universal Biosensors fell more than four percent; Prana and Prima both lost 3.3 percent; Novogen shed two percent; with Avexa and Sirtex down one percent or more.

PSIVIDA

Psivida says that 24-month data from its phase III study of Iluvien presented at Angiogenesis 2010 Miami conference reinforces earlier "positive top-line results".

Psivida said that Johns Hopkins University School of Medicine's Dr Peter Campochiaro presented the 24-month results, based on analysis of the full analysis set representing all randomized patients in the study of Iluvien for diabetic macular oedema.

The company said that "as previously reported, the difference in the percentage of patients in this dataset whose best corrected visual acuity improved by 15 or more letters from baseline on the early treatment diabetic retinopathy study eye chart at month 24 was statistically significant for both doses of Iluvien in each of the two trials … as well as on a combined basis".

Psivida said the study of 956 patients was conducted at 101 sites in North America, Europe and India in two randomized, double-masked, parallel groups.

The primary efficacy endpoint for the FAME Study is the difference in the percentage of patients whose BCVA improved by 15 or more letters from baseline on the ETDRS eye chart at month 24 between the treatment and control groups.

Psivida said that for the combined analysis, 28.7 percent of patients treated with low dose Iluvien, and 28.6 percent of patients treated with high dose gained at least 15 letters, compared with 16.2 percent of control patients (p = 0.002).

Psivida said that based on the 24-month data, its licencee Alimera Sciences would file a new drug application for regulatory approval of the Iluvien low-dose drug by July 2010.

Dr Campochiaro reported that more than 50 percent of Iluvien low dose patients gained at least five letters at 24 months and more than 75 percent of the Iluvien low dose patients received only a single administration of Iluvien.

More than one-third of the one-administration patients with 24 month data gained more than 15 letters at 24 months.

Psivida said that patients receiving low dose Iluvien were also less likely to receive additional treatments for their diabetic macular oedema.

During the 24-month period, about twice as many patients in the control group received laser treatment compared to the low dose Iluvien patients (58.9 percent of control versus 36.7 percent of low dose Iluvien) and more than twice as many patients in the control group received an off-protocol treatment of intravitreal injection of Kenalog or Lucentis or Avastin or vitrectomy, compared to patients in the low dose Iluvien group (28.6 percent of control versus 12.5 percent of low dose Iluvien).

Psivida said additional safety data showed that apart from the previously reported likelihood of increased intraocular pressure, patients receiving low dose Iluvien were slightly more likely to develop glaucoma, which was deemed serious by the reporting physician, than control patients (2.7 percent of low dose Iluvien; 1.1 percent of control).

Low dose Iluvien patients also experienced slightly lower rates of retinal detachment (0.5 percent of low dose Iluvien; 1.6 percent of control) and vitreous hemorrhage (2.1 percent of low dose Iluvien; 2.7 percent of control) deemed serious by the reporting physician.

Psivida said cataracts were common in patients with diabetic macular oedema (DME) and in patients receiving steroids.

About one third of trial patients had cataract surgery before they entered the trial and of the remaining patients, those on Iluvien low dose were twice as likely to develop cataracts as those on control and were three times more likely to have cataract surgery than control patients.

Psivida chief executive officer Dr Paul Ashton said he was "very encouraged by the additional data".

Psivida was up 24 cents or 6.9 percent to $3.70.

BIOMD

Biomd says interim results from its phase II South African paediatric congenital heart defect trial shows Cardiocel treated bovine tissue patch is safe and effective.
Biomd said that between May 2008 and July 2009, 30 patients aged from three months to 14 years received Cardiocel patches.
The company said that follow-up procedures included echocardiographic examination and review at both six and 12 months.
Biomd said more than 20 percent of patients had completed the 12 month assessment and some patients were examined by magnetic resonance imaging (MRI).
The company said all patient follow-up analyses were expected by the end of 2010.
Biomd said the results to date confirmed that the Adapt treated bovine pericardial patch behaved as expected, based on the data and findings in the pre-clinical studies and demonstrated reliable tissue strength and constant stitching characteristics with no reported leakages.
There were no patch related mortalities or morbidities.
Biomd said the results to date confirmed that Cardiocel could target the commercial need for a non-calcifying, implantable biomaterial for paediatric cardiovascular procedures.
Biomd was untraded at 5.4 cents.

EASTLAND MEDICAL SYSTEMS

Eastland says its phase II/III Rwanda clinical trial of sublingual Artimist for malaria has completed treated of the targeted 30 paediatric patients under the age of five years.
Eastland quoted its contract clinical studies provider Protopharma's research and development director Calvin Ross saying completion was achieved within time "due to recruitment being well organized by the clinical trial site staff in Rwanda".
Mr Ross said 15 patients were treated with Artimist spay and 15 with intravenous quinine.
Mr Ross said the clinicians "found Artimist very easy to use and more convenient for the patients compared to an intravenous delivery set up by the bed".
Eastland said the next stage was a full analysis of all collected data including analysis of the blood samples sent to Malaysia for a bio-analytical profile of Artimist in treated patients.
The company said Protopharma reported that the final audited report was expected to be issued by the end of April 2010.
Eastland said that on receipt of the final report and subject to its findings and recommendations, it would establish with Protopharma what further confirmatory, registration-focused clinical work was required, in advance of seeking an interim regulatory licence from the host country.
The company said it would be in a position to engage in preliminary discussions with the World Health Organisation (WHO) regarding its pre-qualification program for essential medicines as well as the Medicines for Malaria Venture and Drugs for Neglected Diseases Initiative.
Eastland said it would "elevate its level of engagement" with pharmaceutical companies that have expertise in tropical diseases and an established foot-print within both the developing countries of Africa and the markets of India, Asia and the Pacific.
The company said it would mandate an Australian corporate consulting group with specific pharmaceutical expertise to advise on establishing a strategic alliance to assist with further project development and commercialization.
Eastland was unchanged at 6.6 cents.

BIOTA

Biota says all the conditions have been met for the acquisition of the antibacterial assets of Boston's Maxthera Inc.

Last year Biota said it had acquired Maxthera's assets and preclinical antibacterial drug development programs for $US1.2 million in cash and $US300,000 in Biota shares, subject to conditions expected "to be met in the near future" (BD: Nov 12, 2009).

Biota said the $US1.2 million ($A1.33 million) in cash had been paid and 155,850 shares would be acquired on market on behalf of Maxthera.

The company said the shares would be released from escrow in two equal tranches in August 2010 and February 2011.

Biota fell one cent or 0.5 percent to $2.15.

ANTEO

Anteo says Bangs Laboratories is actively producing materials using Anteo's Mix&Go technology.

Anteo said Mix&Go allowed proteins or biomarkers to be detected at lower concentrations and across a broader concentration range, with improved stability and reduced lot to lot variability.

The company announced its first licencing deal with Bangs earlier this year and the US company has purchased its initial requirements (BD: Jan 17, 2010).

Bangs president Chad Owen said his company expected to manufacture its "launch requirements of product, have it cleared through quality control and on the shelf within three weeks".

Anteo said Bangs had produced an array of marketing materials to support the launch of the undisclosed product.

The company said Bangs had identified the next bead types it would like to see optimized with Mix&Go by Anteo for subsequent sale and that program was underway.

Anteo fell 0.1 cents or 1.9 percent to 5.1 cents with 11.2 million shares traded.

STIRLING PRODUCTS

Stirling says it has appointed Prof Glyn Tonge as a non-executive director.

Stirling said Prof Tonge had "extensive experience in the international pharmaceutical, healthcare and financial services industries".

The company said Prof Tonge had worked as a research manager for Imperial Chemical Industries (ICI and now Astrazeneca) and for more than 10 years at PA Consulting Group.

Stirling said Prof Tonge was a former director of Baring Brothers and ING Barings where he was global head of pharmaceuticals and healthcare and a director in corporate finance.

He is a director of companies in the UK, Australia and India, including North River Resources and Kalahari Minerals.

Stirling fell 0.1 cents or 7.7 percent to 1.2 cents with 29.0 million shares traded.