Biotech Daily

Thursday July 16, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: POLARTECHNICS UP 13%, PRANA DOWN 8%**

*** POLARTECHNICS MERGER BURIED; FERMISCAN LOSES M-D, CFO**

*** BIOMD UP 129% ON PHASE II CARDIAC PATCH TRIAL SAFETY DATA**

*** COGSTATE PROFIT UP ON WEAKER DOLLAR**

*** PRANA: PBT2 IMPROVES AGE-RELATED COGNITION IN MICE**

*** SOUTH AFRICA DATA BOARD BACKS VIRAX HIV TRIAL**

*** ACRUX COMPLETES DOSING IN PHASE III TESTOSTERONE TRIAL**

*** SOLAGRAN REQUESTS 'STRATEGIC INVESTOR' TRADING HALT**

MARKET REPORT

The Australian stock market climbed 1.81 percent on Thursday July 16, 2009 with the S&P ASX 200 up 71.1 points to 3,995.6 points.

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

Polartechnics was best, up one cent or 13.3 percent to 8.5 cents with 152,000 shares traded followed by Living Cell up 12.5 percent to 18 cents and Labtech up 11.1 percent to 20 cents.

Biota and Viralytics were up more than six percent, the former with 1.5 million shares traded; Circadian and Universal Biosensors were up more than five percent; Alchemia and Phosphagenics both climbed 4.35 percent; Nanosonics and Peplin were up more than three percent; Cellestis and Novogen rose more than two percent; Clinuvel, Heartware and Sirtex were up more than one percent; with Acrux, CSL and Resmed up by less than one percent.

Prana led the falls, down 1.5 cents or 7.9 percent to 17.5 cents with 53,000 shares traded.

Genera lost 5.9 percent; Cathrx fell 4.35 percent; Bionomics, Genetic Technologies and Tissue Therapies shed two percent or more; Starpharma fell 1.5 percent; with Cochlear and Mesoblast down less than one percent.

POLARTECHNICS, FERMISCAN

Following the collapse of the 'friendly merger' of Polartechnics and Fermiscan, the target's managing director David Young and chief financial officer Greg West have resigned.

Polartechnics cited Fermiscan's on-going legal battle against the inventor of its hair x-ray diffraction test for breast cancer, Prof Veronica James, as one contributing factor and said the off-market offer to acquire shares and options in Fermiscan closed yesterday, without reaching the defeating condition of a minimum of 90 percent of acceptances.

Polartechnics said "all takeover contracts and all acceptances that have been received have not resulted in binding takeover contracts and are void".

"All documents sent to Polartechnics by accepting Fermiscan shareholders and option-holders will be returned to them," the bidding company said.

Polartechnics said there had been "a significant decline in Fermiscan's share price during the offer period, which may reflect the loss of its recent court case" (BD: June 18, 29, 2009).

"We understand Fermiscan is appealing against the court decision, the outcome and the timing of any final judgment is uncertain," Polartechnics said.

"The deterioration in Fermiscan's position meant that the merger upon the offer terms was no longer in Polartechnics' best interests," the company said.

Polartechnics is believed to have spent more than $100,000 on the proposed merger apart from the time and effort of its executives.

Fermiscan said managing director David Young along with chief financial officer and company secretary Greg West resigned today.

Fermiscan said that "under the terms of Mr Young's employment, his resignation as an employee will be effective from October 16, 2009".

"Mr Young will not be actively involved in the management of the company between July 16, 2009 and October 16, 2009.

Mr West's resignation as chief financial officer and company secretary will be effective from August 31, 2009 and he will remain actively employed in both roles until that date, Fermiscan said.

Fermiscan has appointed founder and major shareholder Leon Carr as an executive director to fill the vacancy created by Mr Young's resignation.

The company said Mr Carr was an investment banker specializing in corporate advice, capital and business restructures and start up businesses across a broad range of industries and service organizations.

Fermiscan said Mr Carr held 30.7 percent of the company through Rellcain, a company owned by Mr Carr and he also held 10 million options.

Fermiscan said it was seeking suitable replacements for both Mr Young and Mr West.

Polartechnics said acceptances received by the close of the offer period were for 5.72 percent of Fermiscan.

Earlier substantial shareholder notices citing a Polartechnics interest of 22 percent in Fermiscan included the 19.9 percent conditional pre-bid acceptances from Rellcain.

Fermiscan's Leon Carr told Biotech Daily that Polartechnics no longer had an interest in his company.

Mr Carr also disputed the assessment from lawyers for Prof James that the legal liabilities for the New South Wales Supreme Court case would amount to about $1.4 million, suggesting it would be lower, but did not quantify how much.

Fermiscan fell half a cent or 5.9 percent to eight cents.

Polartechnics climbed one cent or 13.3 percent to 8.5 cents.

BIOMD

Biomd says 10 South African children have received its Cardiocel biomaterial patch during open-heart surgery with no related adverse events.

Biomd said the results came from the six monthly follow-up examinations of the first 10 patients in its phase II human clinical trial of the repair of high risk and complex cardiac defects.

Cardiocel is a biomaterial patch made from bovine pericardial tissue and treated with the company's Adapt tissue engineering process.

The company said the six month post-surgical examination included echocardiogaphy assessment, blood biochemistry and a detailed clinical cardiovascular assessment.

Results from the first 10 patients showed no patch-related clinical adverse affects in any of the patients; no patient related thrombo-embolic events; no dehiscence with any implant patch; no flow obstructions; and minimal traces of non-significant mild calcification was observed in some patients.

Biomd said post-operative performance of the implants was evaluated in terms of thrombo-embolic events, immunological reactions, inflammation or endocarditis, dehiscence from the surrounding tissue, degeneration or absorption of the implant and re-occurrence of the pre-surgical anatomical defect, thickening of the implanted graft surfaces obstructing flow patterns and aggressive calcification of the implant.

Biomd said the early results "clearly show within this chronically ill patient group, that the biomaterial performs to expectations when implanted in a demanding cardiac environment and creates no adverse effects".

The company said the Cardiocel biomaterial patch trial was being conducted by the head of the Department of Cardiothoracic Surgery at Universitas Hospital in Bloemfontein, Professor Francis Smit, with the primary objectives being the evaluation of safety, efficacy and clinical performance.

Subsequent follow-up examinations will be undertaken at 12 months post-operatively.

Biomd said 29 patients had been implanted with the Cardiocel biomaterial patch.

"Due to the excellent results obtained from the six month examinations to date and having regard to the health funding crisis currently being experienced in South Africa, the company has agreed with the investigators to conclude the trial upon implantation of the 30th patient," Biomd said.

Biomd managing director Michael Bennett said the results were "very encouraging" and provided the impetus for the commercial production of the Cardiocel patch.

"These preliminary results are a re-confirmation … of our significant pre-clinical findings and we believe they will be sustained through to the 12 month assessments," he said.

Biomd was up 4.5 cents or 128.6 percent to eight cents.

COGSTATE

Cogstate says it expects its net profit after tax for the year to June 30, 2009 to be about $1.38 million.

Cogstate said the unaudited figure was an improvement of more than $2 million on the loss of $750,000 in the previous financial year.

The company said the difference in expected profit to the previously issued guidance in the range of $1.5 million to $1.75 million "was primarily caused by movements in the Australian dollar, relative to the US dollar".

Cogstate said it invoices "almost exclusively in US dollars" and suffered a decrease in margins, particularly in May and June, because of the strengthening Australian dollar.

Cogstate was up 3.5 cents or 14.6 cents to 27.5 cents.

PRANA

Prana says its lead drug for Alzheimer's disease PBT2 is "equally effective in restoring function to normal mice that are cognitively impaired as a consequence of ordinary aging".

In a presentation entitled 'PBT2 ameliorates cognitive impairment in Alzheimer's disease transgenic and aged mice: Evidence for a common mechanism of action' at the International Conference of Alzheimer's Disease in Vienna Prana's head of research Prof Robert Cherny said age-related cognitive loss and Alzheimer's disease were both characterized by alterations in the normal distribution of metals in the brain.

Prof Cherny presented evidence that the beta amyloid protein at the center of Alzheimer's disease pathology exacerbates metal imbalance in the brain.

Prana said PBT2 had been shown to rapidly improve cognition in transgenic Alzheimer's disease mice and the new data showed that PBT2 was equally effective in restoring function to normal mice that are cognitively impaired as a consequence of ordinary aging.

In both cases, the brains of mice treated with PBT2 showed benefits in the area of the brain associated with learning and memory.

Prana said PBT2 restored synaptic spine density, a physical measure of improved neuronal health, to normal levels.

This structural change was accompanied by restoration of neurotransmitter receptors and other markers of neuronal health to the levels seen in healthy young mice.

Prana chief executive officer Geoffrey Kempler said that coupled with phase IIa clinical trial data, "this new evidence of the positive effects of PBT2 on normal aged mice is very exciting".

"Imbalances in brain metals, such as zinc and copper, may affect cognition in Alzheimer's disease patients even before dementia is present," Mr Kempler said.

"PBT2 appears to not only lower amyloid burden in the brain, but also correct metal imbalances that occur in the aged brain and particularly in Alzheimer's where the condition is exacerbated by beta amyloid deposition," Mr Kempler said.

Prana fell 1.5 cents or 7.9 percent to 17.5 cents.

VIRAX

Virax says its South African data safety monitoring board has found no adverse safety data and the 140 patient phase I/IIa trial of VIR201 for HIV can continue without change.

Virax said the trial was designed to assess the safety, tolerability and immunogenicity of VIR201 in two HIV infected groups: patients who have never received antiretroviral treatment and patients currently on a stable antiretroviral treatment regime.

The company said the South African trial design differed from the previous Australian trials of VIR201 in that it used an increased dose of a more highly purified VIR201 vaccine and included both antiretroviral treatment naive and experienced participants.

Virax said a major aim of trial was to compare the immune responses to VIR201 in both patient populations.

The company said the trial data would contribute to the identification of the appropriate time and conditions to vaccinate patients to promote an immune response that can reduce the levels of HIV in infected individuals.

Virax chief executive officer Dr Larry Ward said the data safety monitoring board sign-off was important because it provided safety data for VIR201 at a higher dose than previously used in both antiretroviral treatment naive and experienced treatment populations.

Dr Ward said the recommendations were consistent with there being no reports of serious adverse events attributable to VIR201 to date.

Virax was up 0.3 cents or 9.37 percent to 3.5 cents.

ACRUX

Acrux says it has completed its pivotal phase III open-label trial of Axiron on time, with results expected in September 2009.

Acrux said it recruited more than 150 patients and the majority completed a four months course of its testosterone solution, Axiron.

The company said the phase III open-label trial was conducted at 27 sites in the US, the UK, Sweden, France, Germany and Australia, treating men with below normal testosterone levels.

Acrux said the primary objective was to demonstrate that Axiron restored average blood levels of testosterone to the normal range and the primary endpoint of the trial was the proportion of patients with average blood levels of testosterone within the normal range.

The main trial treatment period was four months, during which blood samples were analysed to determine the level of testosterone in the blood.

Acrux said at least 50 men at the US sites would continue treatment for two months to monitor skin safety with six months of continuous use and four remaining patients were completing the extension study.

Acrux said it expected to submit a marketing application to the US Food and Drug Administration in December 2009 and if approved, Axiron was expected to enter the testosterone therapy market in early 2011.

The company said global sales in the market for the year to March 2009 was more than $US1 billion and sales of testosterone gels grew to $US750 million.

Acrux said the FDA recently announced that it had received reports of adverse effects in children who were inadvertently exposed to testosterone through contact with patients being treated with testosterone gels and was requiring marketers of the gels to include a warning in the product information on the risk of secondary exposure.

Acrux said that in contrast to gels applied by hand on to the upper torso, shoulders or arms, Axiron was a faster-drying solution applied in a small volume to the armpits, using a 'no-touch' applicator.

Acrux said it had previously published results from US market research conducted from patients and physicians, in which 94 percent of patients who tried Axiron rated it better than the testosterone gels in its ability to reduce the risk of transference of testosterone to others.

The company said 92 percent of physicians surveyed who prescribed gels as first line therapy, rated Axiron as very good or excellent in its ability to reduce the risk of transference to others compared to the gels and two-thirds of patients said they would prefer Axiron to their existing gel treatment with 87 percent of physicians saying they would offer Axiron to patients currently using gels.

Acrux chief executive officer Dr Richard Treagus said the commercial value of Axiron "has increased further following the FDA directive to the market-leading testosterone gels".

"We anticipate announcing results from the phase III trial on schedule in September and in parallel we will actively engage the FDA on the benefits of AXIRON, most notably, its greatly reduced risk of secondary exposure," Dr Treagus said.

Acrux said the commercial manufacturing arrangements for Axiron were a key component of the FDA marketing application and the company had completed the transfer of the manufacturing process to Orion Corp in Europe, the exclusive manufacturer of Axiron.

Acrux was up one cent or 0.9 percent to $1.11.

SOLAGRAN

Solagran has requested a trading halt pending an announcement in relation to “to the status of negotiations with a proposed strategic investor”.

Trading will resume on July 20, 2009 or on an earlier announcement.

Solagran last traded at 30 cents.