Biotech Daily

Wednesday June 30, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRANA UP 15%, COMPUMEDICS DOWN 13%**

*** PHOSPHAGENICS STARTS TRANSDERMAL OXYCODONE DOSE TRIAL**

*** CBIO RECRUTIMENT 'MILESTONE'; LUPUS POTENTIAL**

*** FDA: 'CSL DEVIATES FROM GOOD MANUFACTURING PRACTICE'**

*** DAVID LI, BANK OF EAST ASIA CORRECT BIODIEM HOLDING**

*** PSIVIDA'S ALIMERA FILES DIABETIC MACULAR OEDEMA APPLICATION**

*** IM MEDICAL EGM FOR 1.675bn SHARE ISSUE; ELECT DIRECTORS**

*** PROGEN SEALS MEDIGEN PI-88 DEAL**

*** US PATENT FOR CLINUVEL'S SCENESSE**

*** GENETIC TECHNOLOGIES DEALER BAN REDUCED TO 3 YEARS**

*** ACUVAX FUND RAISING; US INVESTEE HAWAII BIOTECH SELLS ASSETS**

MARKET REPORT

The Australian stock market closed the financial year down 1.02 percent on Wednesday June 30, 2010 with the S&P ASX 200 down 44.2 points to 4301.5 points. Ten of the Biotech Daily Top 40 stocks were up, 20 fell, nine traded unchanged and one was untraded.

Prana was best, up two cents or 14.8 percent to 15.5 cents with 188,190 shares traded, followed by Bone up 12.5 percent to nine cents and Cathrx up 10.4 percent to 26.5 cents, both with more than 30,000 shares traded. Sunshine Heart climbed 8.8 percent; LBT was up 6.6 percent; Alchemia and QRX were up three percent or more; Acrux rose 2.8 percent; with Cellestis and Optiscan up more than one percent.

Compumedics led the falls, down two cents or 13.3 percent to 13 cents with 4,500 shares traded, followed by Psivida down 11.1 percent to $3.51 with 1,193 shares traded and Living Cell down 10.4 percent to 21.5 cents with 147,821 shares traded. Cellmid and Circadian lost more than nine percent; Genera fell 6.25 percent; Benitec was down 5.9 percent; Chemgenex, Patrys, Phylogica and Prima fell more than four percent; Bionomics and Pharmaxis were down more than three percent; Tissue Therapies and Viralytics shed more than two percent; with Biota and Cochlear down 0.97 percent.

PHOSPHAGENICS

Phosphagenics has begun recruitment for a pharmacodynamic and dose-ranging trial for transdermal oxycodone for pain.

Phosphagenics said that the opioid oxycodone was one of the world's leading pain management drugs with worldwide sales exceeding $US3 billion ($A3.53 billion) a year.

The company said a previous pharmacokinetic study of daily administration of its tocopheryl phosphate mixture or TPM oxycodone patch to healthy volunteers, demonstrated that it delivered therapeutic levels of oxycodone over a number of days.

Phosphagenics chief executive officer Dr Esra Ogru said the trial would identify the dosing parameters best suited for use in a planned phase II/III clinical trial.

The company said the dose-ranging trial would be conducted at the Royal Adelaide Hospital with principal investigator Prof Guy Ludbrook who is also professor of anaesthesia at the University of Adelaide.

Phosphagenics said the trial was designed to establish the optimal duration that the TPM-oxycodone patch should be left on a patient, as well as the optimal dose of oxycodone required in a patch to provide pain relief.

The study will compare the daily application of TPM-oxycodone patches of different doses as well as comparing the daily-applied patches to patches applied once per week.

Phosphagenics said each subject would be administered with TPM-oxycodone patches for 14 days either daily or once per week.

Phosphagenics said it expected to conduct the phase II/III oxycodone trial early in 2011.

Phosphagenics' research and development vice-president Dr Paul Gavin said the TPM-oxycodone patch appeared to be "very suitable for chronic pain management".

"The results of our TPM-oxycodone trials last year impressed global opinion-leaders in the field of pain management and generated significant commercial interest," Dr Gavin said.

"Our TPM patch system clearly has the potential to change the way in which chronic pain could be treated in the future," Dr Gavin said.

Dr Gavin said that although the patches used in the initial clinical trial might turn out to be optimal, product-profiling of the patch was a necessary step in designing the phase II/III efficacy study "and is critical for our overall program".

"If we can reduce the oxycodone dose or increase the patch duration, this would offer significant regulatory advantages and commercial outcomes," Dr Gavin said.

Phosphagenics was unchanged at 10 cents with 1.9 million shares traded.

CBIO

CBio says recruiting 114 of the targeted 150 patients in its XToll trial for rheumatoid arthritis is a "milestone".

CBio managing director Jason Yeates said the company was "very pleased with recruitment levels achieved by the new clinical trial sites in Central and Eastern Europe as well as the continued support of the trial by sites in Australia".

Mr Yeates said that "there was considerable interest by overseas pharmaceutical companies in the possibility of establishing a parallel research program in other autoimmune diseases such as Lupus".

"At this stage our prime concern is to get the product to market for the treatment of rheumatoid arthritis," Mr Yeates said.

"Given that the same research path might lead to alternative treatments for diseases such as Lupus the company is now investigating what resources would be needed to start an additional program in this area," Mr Yeates said.

CBio fell half a cent or 1.85 percent to 26.5 cents.

CSL

The US Food and Drug Administration has criticized CSL's manufacture of biological vaccine products and monovalent influenza bulks.

A three-page letter from the director of the Office of Compliance and Biologics Quality Center for Biologics Evaluation and Research Mary A Malarkey to CSL's chief executive officer Dr Brian McNamee cited an FDA inspection of CSL Biotherapies in Parkville Victoria between April 19 and 28, 2010 in which investigators "documented deviations from current good manufacturing practice (CGMP) requirements in the manufacture of licensed biological vaccine products and monovalent influenza bulks".

The FDA said the products included Afluria and Influenza A (H1N1) Monovalent Vaccine and cited several US regulations from which it alleged CSL had deviated.

The FDA cited significant deviations observed during the inspection including an alleged failure "to thoroughly investigate any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, and failed to extend the investigation to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy".

"Specifically, your investigation dated April 16, 2010 (initiated January 5, 2010) into the formation of dark particles in Afluria Multi Dose Vials is inadequate," the FDA said.

The full text of the FDA letter is at:
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/UntitledLetters/ucm217293.htm.

In reply, CSL said in a media release on its website dated June 29, 2010, but not announced to the ASX that the inspection related to its seasonal and pandemic influenza vaccines licenced for use in the US and "while regulatory letters of this nature are not uncommon, CSL is taking the issues raised by the FDA very seriously".

"We place the utmost importance on the quality and safety of our therapies and are working actively to resolve the concerns as quickly as possible," CSL said.

"We are currently preparing a detailed response and have made contact with the FDA to arrange a meeting," the company said.

CSL said the FDA had stated that there was "no direct connection between the increase in reports of fever and febrile convulsions reported in young children in Australia this season and the issues raised in the [FDA] untitled letter".

CSL said its investigations had not identified a link between the FDA observations and the increase in side-effects from the vaccines.

CSL said the FDA has released a set of questions and answers in relation to the issues which were available at the FDA's website.

CSL said it had "a strong record of compliance" and would continue to be diligent in its efforts to meet all regulatory obligations.

CSL fell 10 cents or 0.3 percent to $32.58 with 1.4 million shares traded.

BIODIEM

David Kwok Po Li and the Bank of East Asia have corrected yesterday's substantial shareholding which said they held 24,000,000 shares or 31.4 percent.

Today's correction said the total shares on issue had increased and the voting power of the 24,000,000 shares was 25.02 percent.

Biodiem fell one cent or 8.3 percent to 11 cents.

PSIVIDA

Psivida says licencee, Alimera Sciences has submitted a new drug application to the US Food and Drug Administration for Iluvien for diabetic macular oedema.

Psivida spokesman Brian Leedman told Biotech Daily that his company had a 20 percent profit stake in sales of Iluvien.

Psivida said that in the submission, Alimera requested priority review, which, if granted, could result in an action letter from the FDA by the end of this year.

The company said it developed Iluvien and licenced it to the Alpharetta Georgia-based Alimera Sciences in 2005 and the sustained release drug delivery system released the steroid flucocinolone acetonide.

Psivida formally acquired Control Delivery Systems including its drug delivery systems and chief executive officer Dr Paul Ashton, now Psivida's chief executive officer, on December 30, 2005 (BD: Jan 9, 2006).

Dr Ashton said there were no drugs approved to treat diabetic macular oedema (DME), "one of the leading causes of vision loss".

"Iluvien's clinical trials have demonstrated that Iluvien can significantly improve vision in DME patients," Dr Ashton said.

"This is our third product for back-of-the-eye diseases to be submitted to the FDA for approval," Dr Ashton said.

"The first two were approved, are currently on the market and are two of the only three sustained release drug delivery systems currently approved by the FDA to treat back-of-the-eye conditions," Dr ashton said.

Psivida said two pivotal phase three clinical trials for Iluvien involving 956 patients in sites across the US, Canada, Europe and India were being completed to assess the efficacy and safety of Iluvien for the treatment of diabetic macular oedema.

The company said the primary efficacy endpoint was the difference in the percentage of patients whose best corrected visual acuity (BCVA) improved by 15 or more letters from baseline on the approved eye chart at month 24 between the treatment and control groups.

The study will conclude later this year with the final patient visits at the three-year data point, the company said.

Psivida said the 24-month clinical data was announced in December 2009 and the submission to the FDA included the 24-month low dose data (BD: Jan 17, 2010).

The company said that Alimera planned to follow the submission with registration filings in some European countries and Canada in the near future.

Psivida said it had joint ownership and reference rights to this application.

Psivida fell 44 cents or 11.1 percent to $3.51.

IM MEDICAL

IM Medical will hold an extraordinary general meeting to ratify prior share issues and appoint Dr Mark Scott a director.

The resolutions include the issue of up to 1,600,000,000 shares and 3,200,000,000 options to Dr Scott, along with the issue of 75,000,000 shares and options to Pinnacel Equities.

The meeting will also consider the election of Sergio del Vecchio as a director.

The meeting will be held at the Beaumont Room, Quest Beaumont Serviced Apartments, 7 Studley Park Road, Kew, pn July 30, 2010 at 9.30am

IM Medical was unchanged at 0.1 cents with 8.9 million shares traded.

PROGEN PHARMACEUTICALS

Progen has signed a licence and collaboration agreement with Taipei's Medigen Biotech to develop and commercialize the liver cancer compound muparfostat or PI-88.

Progen chief executive officer Sue MacLeman said the binding arrangement put the muparfostat development program "firmly back on track for phase III and commercialization" (BD: Apr 30, 2010).

"Medigen is well positioned to take this important asset forward," Ms MacLeman said.

"They are experienced with the product through their involvement in both its development and phase II clinical trials," Ms MacLeman said.

Medigen and associated investors are a major shareholder in Progen and the Taiwanese company has wanted to acquire PI-88 since Progen discontinued a phase III trial, citing slow recruitment in 2008 (BD: Jul 23, Nov 21, 2008) along with the failed Progen mergers with Avexa and Cytopia.

Medigen was the contract research organization conducting the Taiwan based trial.

Ms MacLeman said in April that Progen's intellectual property costs would be reduced to negligible, but would earn income through wholly-owned subsidiary Pharmasynth manufacturing the active ingredient for Medigen's trials.

Progen said the details of the agreement were confidential but said the deal was "an exclusive worldwide licence and collaboration agreement with sub-licence rights for the commercialization of PI-88 for the therapeutic and prophylactic treatment of cancer".

The company said the royalty rate was "a low double digit rate in territories where there is a valid patent and high single digit in territories where there is not".

In additional to royalty payments, milestones were in place for: regulatory approval to begin the phase III trial; the start of the phase III trial; the completion of the phase III trial; regulatory approval for the product to be marketed; and follow-up market approvals, the company said.

Progen said the 15-year agreement could be terminated if Medigen did not begin a phase III or pivotal registration trial within 12 months.

Progen was up two cents or 5.3 percent to 40 cents.

CLINUVEL PHARMACEUTICAL

Clinuvel says the US Patent and Trademark Office has granted a patent for the use of afamelanotide for people with a genetic defect in the melanocortin-1 receptor.

Clinuvel said the patent covered afamelanotide (Scenesse) and any molecule belonging to the family of melanocortins for ultra-violet light protection of individuals who have any genetic defect in the melanocortin-1 receptor (MC1R) and provided protection until 2024.

The company said the melanocortin-1 receptor played a central role in human pigment response to ultra-violet (UV) light exposure and that 93 percent of fair-skinned individuals with red hair were less protected due to a defect in the melanocortin-1 receptor function and due to their lack of pigmentation.

The company said that melanocortin-1 receptor partial or total loss of function was associated with an increased risk of skin cancer and melanoma.

Clinuvel said its Scenesse, also known as afamelanotide, had been shown to provide photo-protection through increased melanogenesis (melanin activation) in fair-skinned patients diagnosed with UV and light related skin disorders.

Clinuvel chief executive officer Dr Philippe Wolgen the broad scope of the patent covered "all alpha-MSH analogues and provides us substantial commercial leeway in the field of photo-protection".

Clinuvel was unchanged at 22.5 cents.

GENETIC TECHNOLOGIES

The Federal Administrative Appeals Tribunal has reduced a ban on Clive Achalen Henley providing financial services from 10 years to three years, commencing on May 11 2010.
The Australian Securities and Investments Commission said in a media release that the Federal Administrative Appeals Tribunal deputy president Stephanie Forgie upheld the ASIC decision to ban former Tolhurst client advisor Clive Achalen Henley from providing financial services, but reduced the ban period.
Tollhurst was acquired by Patersons Securities in 2009.
ASIC said it banned Mr Henley of Airlie Beach Queensland on January 19, 2009 after the regulator concluded there were grounds to believe he had failed to comply with a financial services law.
ASIC said the ban followed its concerns that in 2006 Mr Henley had engaged in market manipulation by trading shares in Genetic Technologies and that he had falsified order records required to be maintained by the Corporations Act 2001.
ASIC said the Tribunal "was satisfied that he had on two days engaged in conduct that resulted in the creation of an artificial price for the securities of GTG".
ASIC said the Tribunal was also satisfied that Mr Henley had falsified order records on 50 separate occasions by failing to accurately record the identity of the person providing instructions to purchase the Genetic Technologies securities.
ASIC said "the Tribunal also determined that it had reason to believe that Mr Henley will not comply with a financial services law in the future".
ASIC said that on March 17, 2009, Mr Henley successfully applied to the Federal Administrative Appeals Tribunal for an order suppressing publication of ASIC's original banning decision and preventing publication of his name in the AAT.
ASIC said Mr Henley was the third client adviser banned as part of ASIC's investigation into the trading of the securities of Genetic Technologies.
Genetic Technologies was unchanged at 3.5 cents.

ACUVAX

Acuvax says its 26 percent US investee company Hawaii Biotech, which has applied for bankruptcy relief, wants to sell all of its assets.
Acuvax said that it was likely the sale would not generate sufficient funds for a return to shareholders.
Acuvax said it hoped to form a syndicate to bid for some or all of the assets, but "time constraints likely to be imposed as a part of the any sale process will make this an increasingly difficult task".
Acuvax said it would undertaking further capital raising activities including a placement of up to 80,000,000 shares, expected to be at a discount to the current share price.
Following the placement, the company said it expected to undertake a one-for-one non-underwritten, non-renounceable rights issue at the same price as the placement.
Acuvax said the funds would provide the company with sufficient funds to investigate further investment opportunities in its core competency of recombinant technologies.
Acuvax was unchanged at 0.4 cents with 1.5 million shares traded.