Biotech Daily

Wednesday August 20, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS UP: PEPLIN UP 19%, CYTOPIA DOWN 17%**

*** ANADIS SPRAY 'SWITCHES-OFF' MOUSE INFLUENZA VIRUS REPLICATION**

*** PHARMAXIS STUDY SHOWS BRONCHITOL 'SAFE' AFTER 12 MONTHS**

*** VIRALYTICS PHASE I CANCER TRIAL 2nd DOSE COMPLETED; 3rd TO GO**

*** ADVANCED SURGICAL POSTS $190k PROFIT ON REVENUE UP 21.5%**

*** IMUGENE: 'PRRS VACCINE SUCCEEDS IN PIG TRIAL'**

*** BIODIEM, GENZYME DEVELOP BDM-E SCALE-UP**

*** AVANTOGEN PROMISED $1m OF $3m PLACEMENT**

MARKET REPORT

The Australian stock market rebounded 1.4 percent on Wednesday August 20, 2008 with the All Ordinaries up 67.1 points to 4,997.5 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, six traded unchanged and 10 were untraded.

Peplin was best, up eight cents or 19.05 percent to 50 cents in the wake of yesterday's news, followed by Pharmaxis up 8.15 percent to $1.99.

Novogen climbed 7.9 percent; Agenix and Prana were up more than six percent; Psivida was up five percent; Avexa and Biota rose more than three percent; with Acrux, Cochlear CSL, Heartware, Neuren, Progen and Viralytics up more than one percent.

Cytopia led the falls, down 4.5 cents or 16.67 percent to 22.5 cents on small volumes and no news, followed by Polartechnics down 15.38 percent to 11 cents.

Bionomics lost 7.04 percent; Genetic Technologies, Phosphagenics and Ventracor fell more than four percent; Arana, Optiscan and Resmed shed more than two percent; with Alchemia down more than one percent.

ANADIS

Anadis says its cow colostrum nasal antibody spray for immediate post-exposure prophylaxis against a range of influenza viruses is effective in mice.

The University of Melbourne's Department of Microbiology and Immunology has completed a series of proof-in-principal experiments based on mouse influenza challenge models.

The experiments conducted by Prof Loreena Brown used an animal model designed specifically to test influenza prevention and treatment and demonstrated the ability of the antibody spray to "switch-off" virus replication in the respiratory tract lining.

Anadis said its polyclonal antibodies were obtained by vaccinating dairy cows and collecting first-milking colostrum where it was then formulated as a spray dried powder, for later reconstitution as a natural nasal spray.

The studies indicated a significant impact of single and daily dose of the Anadis polyclonal antibodies in reducing the likelihood of infection and reducing the severity of those infected with influenza.

Anadis said its team and University of Melbourne scientists would submit their data for publication and intended to present the details at an influenza control conference.

Anadis' chief executive officer Dr Zeil Rosenberg said the topical spray approach to protecting individuals during seasonal or epidemic flu outbreaks was "a radical new paradigm to protect people from these influenza viruses".

"The fact that the Anadis antibodies are all natural and topically applied means we may have a very safe and effective new approach to provide immediate protection to all persons and be able to address multiple virus strains," Dr Rosenberg said.

He said that current failures in vaccine protection this year showed that new approaches like Anadis' spray were urgently needed.

Anadis was up 0.3 cents or four percent to 7.8 cents.

PHARMAXIS

Pharmaxis says phase III trials of Bronchitol for bronchiectasis have shown no serious adverse events attributed to the drug after 12 months of treatment.

Pharmaxis said a total of 123 subjects started treatment with 320mg Bronchitol twice per day and 99 subjects completed the full 12 months of the trial.

Of the 24 withdrawals, only seven were a result of adverse events of which three related to lung infections and two related to coughs, the company said.

The most common adverse events attributed to treatment were coughs in nine percent of the subjects and sore throats in five percent

Other reported adverse events related to treatment were infrequent, mild in severity and in most cases were a consequence of the underlying disease.

Pharmaxis chief executive officer Dr Alan Robertson said the company intended to file a marketing application in Australia for Bronchitol as "soon as possible now that this study has concluded satisfactorily".

"Bronchitol has created a great deal of interest among people suffering with bronchiectasis and we continue to respond to requests from trial participants and others interested in Bronchitol," Dr Robertson said.

Pharmaxis said the 12-month treatment period was an open label extension to a three month efficacy trial which reported in the second half of 2007.

The trial showed Bronchitol improved quality of life and mucous clearance following three months of treatment and was safe and well-tolerated following 12 months of treatment.

Pharmaxis climbed 15 cents or 8.15 percent to $1.99.

VIRALYTICS

Viralytics says it has completed administration of Cavatak to the second group of patients in its phase I clinical trial in late stage melanoma.

The company has also received approval from the Drug Safety Monitoring Committee to begin escalated dose administration of Cavatak to the three patients of the final group in the trial.

This third and final group of patients will receive a 10-fold higher dose ($2x10^9$ $TCID_{50}$) than the second group and 100-fold higher than the first group of patients.

Viralytics says $VTCID_{50}$ is a measure of potency and stands for the 50 percent mean tissue culture infective dose or the minimum virus required to show cytopathic effect.

Viralytics said the company had administered Cavatak to 13 patients in all trials to date.

The company said administration of Cavatak to the first two groups of patients in this study had determined that there were no severe adverse events considered to be related to the study medication or causing withdrawal from the study.

Viralytics said two injections of Cavatak at a combined dose up to $2x10^8$ $TCID_{50}$ into one subcutaneous lesion in patients with stage IV metastatic melanoma appeared to be well tolerated.

The company said the virus could be detected in some patients up to five weeks post-injection, potentially indicating viral replication.

Viralytics said the primary objective of the phase I clinical trial was to determine safety. Secondary endpoints indicating early stage therapeutic activity will be determined through the assessment of tumour size and signs of viral replication.

The company said that to date, all melanoma patients treated appeared to tolerate either single or multiple intra-tumoural injections of Cavatak up to a combined dose of $2x10^8$ $TCID_{50}$.

Viralytics said it had a second trial underway that recently completed intravenous dosing of two prostate cancer patients.

The company said the trial completed the first group in the intravenous phase I trial of prostate, breast and melanoma patients and it would commence administration to the second group in the trial.

While these preliminary findings are encouraging, it is still too early to draw conclusions regarding the clinical efficacy of Cavatak at this stage, Viralytics said.

Viralytics climbed 0.1 cents or 1.85 percent to 5.5 cents.

ADVANCED SURGICAL DESIGN & MANUFACTURE

Advanced Surgical Design & Manufacture has reported net profit after tax for the 12 months to June 30, 2008 of $180,005 compared to the previous year loss of $419,820.

Revenue was up 21.5 percent to $7.1 million.

Earnings per share was 0.54 cents but no dividend will be paid.

Advanced Surgical's chief financial officer Tom Milicevic told Biotech Daily that it was not the first time in the company's 14 years that it had posted a profit, but there had been significant expenditures in preparing for the company's December 5, 2007 initial public offer as well as ongoing research and development.

Mr Milicevic said the company had been reinvesting earlier profits into the business.

Advanced Surgical was unchanged at 35 cents.

IMUGENE

Imugene says its modified porcine reproductive and respiratory syndrome vaccine has proved “highly effective” in a US-based trial

Imugene said the results showed its modified porcine reproductive and respiratory syndrome (PRRS) vaccine provided “a very high degree of protection against the … disease when two doses are administered either orally or by injection”.

Imugene said porcine reproductive and respiratory syndrome was caused by a viral infection and the major clinical signs were the result of areas of diseased lung (consolidation).

The company said that to evaluate the severity of an infection, standardized lung lesion scores were generated by scoring the diseased areas in each of the seven lung lobes from each pig and then generating an average.

The lower the average lung lesion score the better, as this indicates a lower level of disease. In addition, clinical illness slows weight gain during and after infection.

An effective vaccine should result in less clinical illness and therefore better weight gains following infection, Imugene said.

Following challenge with the live porcine reproductive and respiratory syndrome virus, vaccinated pigs had much lower lung lesion scores and better weight gains over the 14 day post-challenge period compared to the unvaccinated control pigs.

Imugene managing director Dr Warwick Lamb said it was the first time a porcine reproductive and respiratory syndrome vaccine had been “convincingly shown to be effective when administered orally to pigs”.

“The commercial advantages for the pig production industry of a non-injectable vaccine against such an important disease are huge,” Dr Lamb said.

“The modifications made to the PRRS vaccine in the laboratory have translated into much better disease protection in the animal trial,” Dr Lamb said.

“The successful trial result against such a major pig disease is very positive for Imugene’s entire pig vaccine platform,” he said.

“The PRRS vaccine will now be the lead product to progress into the regulatory process for the PAV vaccine range with authorities in the US,” Dr Lamb said.

The trials were undertaken at a specialist trial facility in the US.

A full trial report including statistical analysis is being prepared and is expected in the next 4-6 weeks.

Imugene will use these results in discussions with major international animal health companies with a view to possible licensing agreements.

Imugene said porcine reproductive and respiratory syndrome was one of the most economically damaging pig diseases worldwide causing industry losses of up to $1 billion each year.

Initially recognized in the US in 1987 the disease spread to Europe in 1990 and subsequently across most of the rest of the world.

Australia is one of three countries considered porcine reproductive and respiratory syndrome-free.

The vaccine is based on Imugene’s Porcine Adenoviral Delivery Vector that delivers selected genetic material to the pig to stimulate the immune system to protect against the porcine reproductive and respiratory syndrome virus.

Imugene climbed 2.1 cents or 32.81 percent to 8.5 cents.

BIODIEM

Biodiem and Genzyme Pharmaceuticals say they have developed a solution phase recrystallization protocol suitable for commercial scale manufacture of BDM-E.

Genzyme's senior director of commercial development Dr Marc New said his company was working with Biodiem to develop "long term, sustainable, cost-effective methodologies for large scale manufacture of small peptides".

The Swiss-based Genzyme specializes in peptide synthesis, lipid and small molecule active pharmaceutical ingredient manufacture.

Biodiem's chief executive officer Dr Andrew O'Brien said that producing a "cost effective, scalable [good manufacturing practice] protocol for the manufacture of drug candidates is an often overlooked component of commercial drug development by early stage biotechnology companies".

"A low cost manufacturing protocol that meets the requirements of international regulators is a key element in successfully bringing a commercially viable product to market, either in-house and/or in partnership," Dr O'Brien said.

He said that the outcome had allowed Biodiem increased flexibility in defining the appropriate dose for BDM-E when entering the clinic.

Last year, a Russian trial of BDM-E for diabetic macular oedema failed to meet its endpoints (see Biotech Daily October 9, 2007).

The trial was a phase I/II double-blind, placebo-controlled trial of BDM-E at 10 µg/day by subcutaneous injection for 10 days. BDM-E was safe and well-tolerated with no significant adverse events. Biodiem chief executive officer Dr Andrew O'Brien said at that time the dose was chosen two years earlier and that a scale dose trial would be required.

Biodiem was untraded at 9.5 cents.

AVANTOGEN

Avantogen says it has a commitment of $1 million of a proposed $3 million placement at five cents a share.

Avantogen said the 20,000,000 share placement was arranged by financial advisor BBY and supported by institutional funds and investors.

Last month, Avantogen chief executive officer Dr William Ardrey said his company owned 33 percent of Hawaii Biotech and the capital raising with BBY (formerly Burdett Buckeridge Young) was to acquire more stock in the company that has a phase I trial for West Nile Fever and expects to begin a phase I trial in Dengue fever patients in November 2008 (see Biotech Daily; July 29 and 30, 2008).

Dr Ardrey told Biotech Daily today that the company intended to raise about $3 million and was continuing discussions with potential investors.

In December 2007 the company said it intended to place $8 million in shares, which was restated when a $1 million placement at five cents a share was announced (see Biotech Daily February 12, 2008).

Dr Ardrey told Biotech Daily today that his company's business model was based on early licencing and return of revenue.

An Avantogen media release said that the initial shares would be allotted immediately to new investors and shares would be allotted in tranches.

Avantogen jumped four cents or 100 percent to eight cents with 41,000 shares traded.