Biotech Daily

Friday December 5, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: ANTISENSE UP 11%, STARPHARMA DOWN 19%**

*** PROGEN v COUP GROUP: ROUND 2; JANUARY 9, 2009**

*** HEARTWARE COMPLETES EURO-ENROLMENT; AWAITING CE MARK**

*** PHYLOGICA ACQUIRES DYNAMIC MICROBIALS; LOSES DIRECTOR**

*** BIODIEM FLU VACCINE 'MAY CONTROL PANDEMICS'**

*** CAPITAL GROUP CLIENT TAKES 10% OF COCHLEAR**

*** SOLAGRAN DIRECTOR CHARLES PELLEGRINO RESIGNS**

*** GOODBYE AVANTOGEN; G'DAY ACUVAX**

MARKET REPORT

The Australian stock market fell 1.2 percent on Friday December 5, 2008 with the All Ordinaries down 40.9 points to 3,427.2 points.

Five of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and seven were untraded.

Antisense was best, up 0.4 cents or 11.43 percent to 3.9 cents with 180,000 shares traded, followed by Tyrian up 0.3 cents or 10 percent to 3.3 cents.

Novogen climbed 7.89 percent; Acrux was up 4.44 percent; with Ventracor up 1.39 percent.

Starpharma led the falls, down 4.5 cents or 19.5 percent to 19 cents with 3,175 shares traded, followed by Viralytics down 18 percent to 4.1 cents, Neuren down 13.33 percent to 5.2 cents, with Cytopia and Genetic Technologies both losing 10 percent to 18 cents and 4.5 cents, respectively.

Pharmaxis lost 9.68 percent; Labtech was down 8.33 percent; Alchemia and Living Cell fell more than seven percent; Chemgenex, Polartechnics and Sirtex were down more than five percent; Biota and Clinuvel fell more than four percent; Mesoblast, Psivida and Resmed were down more than three percent; Benitec shed 2.94 percent; with CSL, Prana and Progen down more than one percent.

PROGEN

Progen shareholders will vote to keep or replace the board at an extraordinary general meeting on January 9, 2009.

Progen has brought forward the last date for announcing whether it has a suitable acquisition and/or merger plan or would return all of its $70 million in cash to shareholders to January 8, instead of the previously announced 45 day limit of January 14, 2009 (see Biotech Daily; November 24, December 1, 2008).

Progen chief executive officer Justus Homburg told Biotech Daily that shareholders would be told of any acquisition or merger plan prior to the meeting requisitioned by the "coup group" which has proposed a new board led by Antisense chairman Bob Moses and former EG Capital analyst Alison Coutts, now with Martin Place Equities.

Mr Homburg said shareholders would then have a choice of supporting the existing board's decision of a proposed acquisition or merger; or receiving about $1.10 per share; or electing the coup group's proposed directors to implement their alternative plan.

The coup group's plan includes licencing Progen's PI-88 to a small pharmaceutical company, identified in today's announcement to the ASX by Progen as a privately-owned Taiwanese company.

The plan also identifies Progen's 500 series compounds as of interest to other parties and Mr Moses told Biotech Daily on December 1 that the group would integrate several public and private cancer therapeutics companies to create a single company focused on advanced polysaccharides for treating cancers.

Progen said the coup group describes itself as the Progen Shareholders Group.

In a point-by-point response to the coup group proposal, Progen said that the Progen Shareholders Group disclosed that an unsecured loan of $US3 million ($A4.6 million) to conduct a phase III trial, would be made to the unnamed Taiwanese pharmaceutical company "only repayable from royalties derived form the commercial sale of PI-88".

Progen said there appeared to be no interest charged on the loan.

Progen said that agreement was "likely" to trigger a $2 million payment to Medigen which previously worked with Progen on PI-88.

Medigen chief executive officer Dr Stanley Chang removed himself from the proposed list of replacement directors following Biotech Daily's disclosure of a potential conflict of interest over the $2 million payment to Medigen.

Progen said the Progen Shareholders Group also proposed that Progen be granted options to buy shares in the Taiwanese company.

"We have seen opportunistic deal terms such as these before and when we model the expected cash-flows to Progen we find that there is no financial return and consequently we conclude that such deals are often not in the best interests of shareholders. Of great concern is the apparent lack of security over the loan," Progen said.

Progen also said that the coup group did not appear to intend to retain Mr Homburg as chief executive officer and he may be entitled to a termination payment of $147,000.

The resolutions to the meeting call for the removal of chairman Dr Mal Eutick and directors Robert Williamson, Stephen Jun Chi Chang, Patrick Owen Burns and chief executive officer Justus Homburg.

The coup group has called for the appointment of Mr Moses, Ms Coutts and Dr Woei-Jia Jiang as directors.

The extraordinary general meeting will be held at the Terrace Room, Indooroopilly Golf Club, Meiers Road, Indooroopilly, Queensland on January 9, 2009 at 10am.

Progen fell 1.5 cents or 1.76 percent to 83.5 cents.

HEARTWARE

Heartware has completed enrolment of 50 patients for the Conformitée Européenne clinical trial of its left ventricular assist device.

The company said the 50 patients implanted with the Heartware ventricular assist device (HVAD) at five centres in Europe and Australia had been supported for an average of 250 days each.

Heartware said a total of 12 patients have received heart transplants after being supported for an average of 266 days each.

Three patients had their device removed after recovery of their heart function.

Four patients died on support within the first 180 days of their implant.

One additional patient death occurred beyond 180 days.

Thirty-one patients have successfully met the endpoint of the trial of 180 days or transplant.

A further 15 patients remain on support but have yet to reach the 180 day endpoint.

Heartware chief executive officer Doug Godshall said that with 50 patients implanted in the trial, representing a cumulative support period of 35 years, “we are becoming increasingly confident of the performance of this device given our positive early clinical data”.

He said that at the International Society for Heart and Lung Transplantation conference in April this year Dr Georg Wieselthaler presented data from Heartware’s first 23 patients, showing a survival to endpoint of more than 90 percent.

“It is pleasing that this unusually high rate of success continues to hold true over the larger patient group, particularly in light of the relatively small number of transplants that have occurred,” Mr Godshall said.

Heartware’s application to apply the Conformitée Européenne (CE) Mark to the Heartware System was based on data from the first 25 patients and the data was presently under independent clinical review.

Heartware said it reiterated its expectation “that CE Mark will be granted in the weeks ahead”.

Previously, Heartware said it expected CE Mark approval by the end of 2008.

Today Heartware told Biotech Daily that the company still expected that to be the case, but if approval was delayed by the Christmas holiday period, approval would be by mid-January 2009.

With the completion of the trial, Heartware said its two core areas of focus were to manage the company’s US clinical trial and, in parallel, to drive an effective commercial launch and subsequent rollout in Europe and Australia following receipt of CE Mark.

Heartware was unchanged at 50 cents.

PHYLOGICA

Phylogica says it has issues 20,250,000 shares to complete the acquisition of Dynamic Microbials Limited.

Phylogica said in November that it would acquire Dynamic Microbials, a private, Perth-based company “that had licenced certain anti-microbial rights” to the company’s Phylomer technology (see Biotech Daily; November 24, 2008).

Phylogica also said Dr Mark Pierce resigned as a director effective December 4, 2008.

Phylogica was untraded at five cents.

BIODIEM

Biodiem says phase II studies of an H5N2 live influenza vaccine candidate show it “may be effective in helping to control a pandemic outbreak of influenza”.

Biodiem said the safety and immunogenicity data published in the peer reviewed Journal of Influenza and Other Respiratory Viruses were completed at the Institute of Experimental Medicine in St Petersburg, Russia under a protocol approved by the Medical Ethics Committee of the Ministry of Health of the Russian Federation.

The phase II trial was conducted as a double-blind control study with 100 participants aged 18-49 years assigned in a 2:1 ratio of vaccine or placebo.

Peripheral blood specimens and nasal swabs were collected from volunteers before vaccination, 21 days after the first dose vaccination and 21 days after the second dose of vaccination. Volunteers in each group were given two doses of vaccine 21 days apart or two doses of placebo.

The immunogenicity of the vaccine was tested through assessing sera for hemagglutination-inhibition (HI) of H5 specific antibodies; determining virus neutralizing antibodies to H5N2 and H5N1 through micro-neutralization assays; and identification of influenza virus-specific IgA antibodies in nasal swabs by enzymelinked immunosorbent assays (ELISA).

The key results of the study indicate that the vaccine was safe and lowly reactogenic with no fever reactions.

After revaccination 47.1 percent to 54.8 percent of subjects showed an equal to, or greater than, four-fold seroconversion of HAI antibodies to A(H5N2) antigen and 29.4 percent to 30.4 percnet were seroconverted to A(H5N1) antigen.

Biodiem said virus neutralizing antibodies levels in sera of volunteers were similar to those shown in the HAI test and the virus-specific nasal IgA antibody response after two vaccine doses demonstrated significant increases of an equal to or greater than four fold rise in SIgA antibodies, 65 percent geometric mean titres and a rise in SIgA antibodies compared to a single dose.

Biodiem director and Head of Virology Department at the Institute of Experimental Medicine Prof Larisa Rudenko said “a live attenuated influenza vaccine candidate prepared using non-pathogenic avian A (H5N2) strain was well-tolerated in these studies”.

“The vaccine elicited clear serum and local immune responses, whilst also showing cross-reactivity to the A(H5N1) antigen in the HAI test,” Prof Rudenko said.

Biodiem managing director Dr Andrew O’Brien said the results “demonstrate that a live attenuated vaccine may be effective in helping to control a pandemic outbreak of influenza”.

“The data from Prof Rudenko and colleagues accepted for publication in the Journal of Influenza and Other Respiratory Viruses further illustrates the world leading work being completed at the IEM for Biodiem in the field of influenza vaccine research,” Dr O’Brien said.

Biodiem was untraded at seven cents.

COCHLEAR

The US based Capital Group Companies has increase its substantial shareholder in Cochlear from 4,927,063 shares (8.82%) to 5,563,218 (9.94%) on December 3, 2008.

On November 3, 2008 Capital Group increased its Cochlear holding from 7.75 percent to 8.82 percent. The Capital Group said it did not own shares in Cochlear but held them on account for Capital Research and Management Company.

Cochlear fell 50 cents or 0.96 percent to $51.50.

SOLAGRAN

Solagran says Charles Pellegrino resigned as a director on December 1, 2008.
In the final director's interest notice Mr Pellegrino was recorded holding no direct shares, but held an interest in 40,000 shares held by Medco Financial Services.
On July 20, 2007, Mr Pellegrino held an indirect interest in 3,966,361 ordinary shares and 3,562,090 contributing shares through ANZ Nominees, Solamind and Medco Financial Services.
Solamind gave its 42 percent holding in Solagran to Opes Prime Stockbroking, which collapsed, passing its shares to the ANZ Bank (see Biotech Daily; April 4, 2008).
Solagran did not publish a formal announcement of Mr Pellegrino's departure as a director.
Solagran climbed two cents or 12.12 percent to 18.5 cents.

AVANTOGEN, ACUVAX

Avantogen has formally changed its name to Acuvax.
Acuvax chief executive officer Dr William Ardrey told Biotech Daily the name more accurately reflected the company's business focus.
The ASX code remains the same, ACU.
Acuvax fell 0.4 cents or 13.33 percent to 2.6 cents.