Biotech Daily

Friday March 6, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 25%; CYTOPIA DOWN 29%**

*** PEPLIN GEL REDUCES 84.5% OF HEAD LESIONS; READY FOR PHASE III**

*** PRIMA RECOMMENCES CVAC TREATMENT**

*** OPES PRIME PUNTERS MAY GET 40% BACK**

*** PROGEN PAYS FOR PRO-AVEXA MERGER PROXIES**

*** SEVEN BIOTECHS PROMOTED TO S&P ALL ORDINARIES INDEX**

*** CYTOPIA, PROGEN, AVEXA AWAIT INJUNCTION HEARING RESULT**

*** METABOLIC: POLYNOVO LOSES CEO DR IAN GRIFFITH**

MARKET REPORT

The Australian stock market fell 1.35 percent on Friday March 6, 2009 with the S&P ASX 200 down 43 points to 3,145.5 points.

Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, four traded unchanged and eight were untraded.

Antisense was best, up 0.8 cents or 25 percent to four cents with 100,000 shares traded, followed by Genetic Technologies up 19.35 percent to 3.7 cents and Phylogica up 19.1 percent to five cents.

Alchemia climbed 9.09 percent; Benitec and Viralytics were up more than eight percent; Genera was up 4.55 percent; Clinuvel and CSL rose more than two percent; Peplin was up 1.1 percent; with Arana, Cochlear and Pharmaxis up less than one percent.

Cytopia led the falls, down 2.5 cents or 29.41 percent to six cents with 200,000 shares traded followed by Optiscan down 16 percent to 4.2 cents with Living Cell and Nanosonics down 11.11 percent to eight cents and 28 cents, respectively.

Progen lost 8.33 percent; Cellestis was down 6.76 percent; Acrux fell 4.44 percent; Avexa, Chemgenex, Heartware, Prana, Resmed and Sirtex were down more than three percent; Polartechnics and Starpharma shed more than two percent; with Mesoblast, Novogen and Universal Biosensors down more than one percent.

PEPLIN

Peplin says it will take PEP005 Gel to a phase III trial following dose ranging results from its phase IIb trial for actinic or solar keratosis lesions on the head.

Peplin said a 0.015% concentration of PEP005 (ingenol mebutate) Gel applied once daily for three consecutive days has been selected for the phase III trial.

The company said this concentration and dosing regimen "provided a median reduction in overall lesion count of 84.5 percent, a total clearance rate in the intent-to-treat population equal to 50.0% ($p < 0.001$) and a partial clearance rate of 71.9% ($p < 0.001$)".

Peplin said the local skin responses peaked at Day four and returned to baseline by Day 15 for all treatment groups.

The company said actinic keratosis was "a common pre-cancerous skin condition caused by sun exposure".

The face is the most common area for sun damage and the most common area for actinic keratoses, which can develop into skin cancers if left untreated, the company said.

Peplin chief executive officer Tom Wiggans said the comprehensive analysis of the trial provided additional support for the potential of PEP005 Gel to help physicians and patients dissatisfied with the current actinic keratosis treatment options.

"No current product on the market has a short course of therapy as well as proven safety and efficacy for both head and non-head lesions," Mr Wiggans said.

"The potential value that PEP005 Gel offers patients is considerable," Mr Wiggans said.

The company said that assuming a successful end-of-phase II meeting with the US Food and Drug Administration on May 20, 2009, it planned plans to use this dosing regimen to initiate subsequent phase III clinical trials for patients with actinic keratosis lesions on the head by July 2009.

Peplin said it had recently completed enrolment in its first phase III trial of PEP005 Gel for actinic keratosis lesions on non-head locations, which was being conducted under a special protocol assessment with the FDA with results expected by July 2009.

The company said the PEP005-015 phase IIb trial was an eight-arm, 240-patient, US and Australian multi-centre, randomized, double-blind, vehicle-controlled, dose-ranging clinical trial, designed to evaluate the safety and efficacy of each of three concentrations (0.005%, 0.010% or 0.015%) and two treatment regimens of either once a day for two consecutive days or once a day for three consecutive days.

Patients with actinic keratosis lesions on the face and scalp were centrally randomized to treatment and stratified across treatment groups based on treatment area location .

About 20 percent of patients were treated on the scalp and 80 percent were treated on the face.

There were no treatment-related serious adverse events and adverse events were generally mild to moderate in severity and resolved by Day 57.

The most common treatment-related adverse events, occurring within the treatment area, appeared to be application site irritation and pruritus.

Other treatment-related adverse events included peri-orbital swelling or swelling around the eye/eyelids, adjacent to the treatment area.

In all cases, the treatment-related events resolved without further sequelae, Peplin said.

A 0.015% concentration of PEP005 Gel applied once daily for three consecutive days resulted in a total clearance rate in the intent to treat population equal to 50.0 percent ($p < 0.001$) and a partial clearance rate of 71.9 percent ($p < 0.001$).

The selected dose provided a median reduction in overall lesion count of 84.5 percent.

Peplin climbed half a cent or 1.1 percent to 46 cents.

PRIMA BIOMED

Prima has commenced patient treatment with its CVac ovarian cancer therapy under an Australian Therapeutic Goods Administration special access scheme.

Prima director Martin Rogers told Biotech Daily that two or three patients were being treated through compassionate use, ahead of trials expected later this year.

In March 2007 Prima's full phase IIa clinical trial results showed statistically significant ovarian cancer reduction and the company said it would raise $10 million for a pivotal trial scheduled for that year (BD: Mar 14, 2007).

The company said four of 21 patients (19 percent) showed a response, Prima said its Cvac treatment had exceeded expectations, but the company was unable to make progress.

A year later Prima appeared to be on the road to recovery with a new board, cash in the bank and a planned pivotal phase II/III trial of its ovarian cancer vaccine (BD: May 14, 2008). Mr Rogers said at that time the company had raised $2.3 million.

Today, Prima said it was "making rapid progress towards the commercialization of CVac, including a successful pre-investigational new drug application meeting with the US Food and Drug Administration late last year.

Prima said the patient treatment was "another important step in the commercialization process".

The company said the injection of the CVac vaccine in ovarian cancer patients worked "as a post-surgery and post-chemotherapy maintenance therapy to delay relapse and control metastases".

Prima said ovarian cancer had a very high morbidity rate and there was "a massive un-met global market" with no ovarian cancer maintenance therapy products available.

Prima was up 0.2 cents or 33.33 percent to 0.8 cents with 2.4 million shares traded.

PROGEN, AVEXA

Progen says it is offering a stamping fee to stockbrokers for shareholder proxy votes in favor of the Avexa merger.

Progen and Avexa announced a merger on December 22, 2008 and a group of Progen shareholders led by Cytopia proposed a hostile merger on January 28, 2009.

A war of words has continued with Avexa and Cytopia vying for a share of Progen's $70 million in cash while three institutional investors appear to want a return of capital.

Several brokers contacted by Biotech Daily said that while stamping fees were common for processing paper work, they had not previously seen a fee being paid for proxy votes and certainly not for votes in a particular direction.

Progen chief executive officer Justus Homburg told Biotech Daily that Progen had proposed the stamping fee and said there were many precedents for the procedure.

An email provided by a stock-broking firm said: "With respect to the recent merger announcement between Avexa and Progen, any 'pro-merger' voting forms returned by clients who own Progen shares will attract a stamping fee. The stamping fee is 0.75% of the total value of the shares with a minimum of $40 and a maximum of $500. This will be paid only if the forms vote 'pro-merger'. Voting forms should be submitted by the weeks end [March 6] to ensure payment of the stamping fee."

Asked about the payment for votes of a particular direction, a spokeswoman for the Australian Securities and Investments Commission told Biotech Daily: "As long as it's adequately disclosed to shareholders it is not illegal."

"Disclosure is the main concern," the ASIC spokeswoman said.

Progen fell seven cents or 8.33 percent to 77 cents.

OPES PRIME

The Australian Securities and Investments Commission says Opes Prime creditors may receive up to 40 cents in the dollar lost in the collapse of Opes Prime Stockbrokers.

“Based on estimates provided by the liquidator, the settlement, if approved by creditors and the court, is expected to deliver a sum of $253 million and a return of around 40 cents in the dollar to creditors of Opes Prime, which includes investors,” ASIC said.

“This return is based on the value of potential creditors claims as at March 27, 2008 when Opes Prime went into administration.”

At the time of publication Biotech Daily had not been able to determine from ASIC or the administrators Ferrier Hodgson whether investors who gave their shares to Opes Prime would receive a 40% return on the March 27, 2008 share price.

It is believed that secured creditors and individual participants in the Opes Prime margin lending schemes may be treated equally (BD: April 4, 8 and 10, 2008).

If that is the case some Opes Prime clients will be better off having lost their shares to regain 40 percnet of their value compared to the share price fall.

ASIC said it would provide the necessary releases to allow a settlement offer to be put to Opes Prime investors.

This settlement offer is subject to both the approval by Opes Prime creditors and court approval of a creditors scheme of arrangement giving effect to the offer, the regulator said.

The total value of known biotechnology shares given to Opes Prime, not including Solagran’s 10 million contributing or partly paid shares was about $70.8 million with an expected total return of $28.3 million if the 40 percent figure relates directly to share holdings at that time, without higher ranking creditors being paid first.

On March 27, 2008 the biggest Opes Prime biotechnology loser was Solagran’s Solamind which had given the stock-broking firm 56.1million ordinary shares and 10 million partly paid or contributing shares. Solagran closed at 89 cents on that day making its loss $49.9 million.

Acrux chairman Ross Dobinson lost 14.6 million Acrux shares worth $1.025 and 2.8 million Starpharma shares worth 32 cents each at that time for a total loss of $15.8 million.

Bioprospect’s 124.5 million shares were worth $4.0 million, Incitive’s 4.25 million shares were worth $149,000, Norwood Abbey’s 17.5 million shares were valued at $367,500 and Rockeby’ 39.3 million shares were worth $550,200.

The proposed settlement follows mediation initiated by ASIC between it, the ANZ Banking Group, Merrill Lynch (International) Australia and the liquidator of Opes Prime Stockbroking.

These mediation processes have been progressed by the liquidator and the banks, ASIC said.

STANDARD & POOR’S ALL ORDINARIES INDEX

Seven biotechnology companies have been promoted to the Standard and Poor’s All Ordinaries index of Australia’s top 500 companies by market capitalization.

The only biotechnology company to exit the All Ordinaries was Avexa, which has experienced a significant price fall over the past 12 months.

Vision Group which is involved in eye surgery also fell from the All Ordinaries list.

The additions to the index were Clinuvel, Chemgenex, Heartware, IDT, Mesoblast, Novogen and Prana.

Pro Medicus which develops radiography software was also promoted to the All Ordinaries index.

CYTOPIA, PROGEN, AVEXA

At the time of publication, a hearing in the Federal Court in Melbourne was unresolved on a Cytopia injunction to prevent Progen hold the March 11, 2009 Avexa merger meeting.
The injunction seeks to prevent Progen from holding the meeting and to require Progen to include the resolutions which were to be considered at the merger meeting on the agenda for the requisitioned general meeting to be held on March 27, 2009 (BD: March 5, 2009).
Progen is opposing the application.
Cytopia fell 2.5 cents or 29.4 percent to six cents.
Progen fell seven cents or 8.33 percent to 77 cents.
Avexa fell 0.3 cents or 3.95 percent to 7.3 cents.

METABOLIC, XCEED, POLYNOVO

In an announcement after the market closed, Metabolic said Polynovo chief executive officer Dr Ian Griffiths “has left the company with immediate effect”.
Metabolic owns 60 percent of Polynovo and said the board of Polynovo had appointed Metabolic non-executive director Iain Kirkwood as interim chief executive officer with immediate effect.
Mr Kirkwood has also been appointed to the board of Polynovo.
Xceed Capital owns 25.5 percent of Polynovo and the Commonwealth Scientific and Industrial Research Organisation holds the remaining shares.
Metabolic said a “full strategic review will be conducted in conjunction with the search for a new CEO”.
Metabolic said Laurent Fossaert remained as Polynovo’s chief operating officer.
Metabolic fell 0.2 cents or 8.7 percent to 2.1 cents.
Xceed was unchanged at 1.3 cents.