Biotech Daily

Monday August 31, 2009

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: BENITEC UP 49%, BONE DOWN 17%**

*** CLINUVEL PREEMPTS EURO REGULATOR WITH 2nd PHASE III TRIAL**

*** FDA APPROVES PRIMA PHASE IIb OVARIAN CANCER TRIAL**

*** BIODIEM COMPLETES PHASE I 'FLU VACCINE RECRUITMENT**

*** UNILIFE POSTS $13m PROFIT ON REVENUE UP 869% TO $40m**

*** TYRIAN UNDERWRITTEN RIGHTS ISSUE RAISES $5m**

*** CBIO TO RAISE 'MORE THAN $6m'; LIST ON ASX; RESTART TRIAL**

*** AVITA LOSS DOWN 58% ON REVENUE UP 67% TO $3.3m**

*** PHARMAUST LOSS DOWN 97% ON REVENUE UP 25% TO $3.7m**

*** FURTHER US, JAPAN RNAi PATENTS FOR BENITEC**

*** BIOPHARMICA APPOINTS DEBORAH AMBROSINI AS A DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.23 percent on Monday August 31, 2009 with the S&P ASX 200 down 10.5 points to 4479.1 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and five were untraded. All three Big Caps fell.

Psivida was best for the second consecutive trading day, up 30 cents or 10.34 percent to $3.20 with 5,000 shares traded, followed by Impedimed up 9.3 percent to 59 cents.

Tissue Therapies climbed 7.1 percent; Novogen and Sunshine Heart were up more than six percent; Progen climbed 4.9 percent; Labtech was up 3.6 percent; with Prana up 2.13 percent.

Bone led the falls, down four cents or 16.7 percent to 20 cents with 92,700 shares traded, followed by Mesoblast down 7.2 percent to 90 cents.

Phylogica lost 6.25 percent; Compumedics and Tyrian both fell 5.3 percent; Biota and Phosphagenics fell more than four percent; Alchemia and Chemgenex were down more than three percent; with Cochlear and Pharmaxis down more than two percent.

CLINUVEL

Clinuvel says it will run a second confirmatory phase III clinical trial of afamelanotide for erythropoietic protoporphyria, without a request from a regulatory agency.

In a media release to the ASX, Clinuvel said it would run a multicentre phase III trial with up to 70 patients despite a similar trial which began in April 2007 due to be completed by October 2009.

Clinuvel said erythropoietic protoporphyria was "a rare metabolic disorder rare genetic disease found in people with fair skin, which causes protoporphyrin IX to accumulate in the skin and was characterized by severe light-sensitivity or phototoxicity of the skin resulting in intolerable pain, swelling, and scarring, usually of the hands and face".

The company said the second phase III trial would "further evaluate the reduction in the severity of phototoxic reactions".

Clinuvel said that pending results of its first trial by October 2009, the regulatory submission for marketing authorization in Europe would "follow shortly after".

In its media release Clinuvel's chief scientific officer Dr Hank Agersborg said the company was "organizing an additional trial ahead of the results in our first phase III trial".

"Our clinical and regulatory team has been proactive in trying to anticipate the most stringent of regulatory requirements," Dr Agersborg said.

"We are not prepared to wait for a possible equivocal review panel, but anticipate what might come," he said.

"The parallel planning of an additional trial - while not being requested - is the most cost-efficient way and forward management I have been involved in," Dr Agersborg said.

"It stands in contrast to traditional waiting for the regulatory verdict when being asked to generate more clinical data after regulatory review," he said.

"Our approach translates to a potential 12 month gain in development," Dr Agersborg said.

"This strategy also meets our broader clinical objectives to subject as many EPP patients as feasible to afamelanotide during the testing phase to collect optimum safety data," Dr Agersbord said.

"The six month trial … will start in five centres across Europe shortly and it is anticipated that approximately 40 patients will be included in this trial," Dr Agersborg said.

In a written response, Clinuvel told Biotech Daily that it had noted that at least two Australian companies had been asked to undertaken additional trials despite the quality of their data.

To the best of Biotech Daily's knowledge, Pharmaxis and Peplin have been asked by the US Food and Drug Administration to undertake additional trials and Halcygen reported on Friday that the UK regulator wanted it to demonstrate its drug was equal to European versions of its competitor as well as the US version.

Biotech Daily does not know of any other Australian company that has been asked by European regulators to conduct a confirmatory trial.

"No one has ever asked us to do this, but it's part of prudent management. It's better to pre-empt. This strategy saves time and resources, rather than being forced to do another trial after regulatory review," Clinuvel said.

Clinuvel said afamelanotide was granted orphan drug status for erythropoietic protoporphyria by the European Medicines Agency, Swissmedic and the US Food and Drug Administration.

Clinuvel fell 0.5 cents or 1.54 percent to 32 cents.

PRIMA BIOMED

The US Food and Drug Administration has approved Prima's phase IIb clinical trial of its CVac ovarian cancer vaccine treatment.
Prima said the phase IIb trial would be conducted with 60 patients at the Fred Hutchinson Cancer Centre in Seattle and would be managed by the company's head of US operations Ginny Raymond, Pfizer's former director of global medical operations.
The company said the trial would add to the positive efficacy results from Prima's Australian phase IIa trial.
Subject to the trial's results the company said it hoped to commence commercial scale treatment of ovarian cancer patients in Australia and New Zealand.
Prima said the trial was designed to further confirm the ability of CVac to reduce the instance of relapse in ovarian cancer patients, control the metastases of the cancer and increase the life expectancy of patients.
The company said CVac was a vaccine therapy treatment for ovarian cancer sufferers administered post-surgery and post-chemotherapy to delay the relapse and control the metastases of the cancer.
Prima was up 0.4 cents or 4.2 percent to 10 cents with 39.2 million shares traded.

BIODIEM

Biodiem says it has completed recruitment for its phase I trial of its intranasal live attenuated influenza vaccine SCH 900795.
Biodiem said the trial was a randomized, double-blind, placebo-controlled, single rising dose design 120 healthy volunteers.
The company said the primary objective was to investigate safety, tolerability and immunogenicity of escalating doses of this vaccine in adult men and women.
Biodiem said SCH 900975 was being developed by Nobilon, the human vaccine business unit of Schering- Plough and it had licenced the majority of the live attenuated influenza vaccine (LAIV) rights to Nobilon.
The company said that it was analyzing the data and a phase II trial was planned to coincide with the next northern hemisphere influenza season.
Biodiem said SCH 900795 was composed of three attenuated or weakened influenza viruses chosen according to recommendations of the World Health Organization for seasonal vaccine.
The company said its vaccine was a single-dose intranasal spray delivery, which was more convenient for people being vaccinated, and had an advanced cell culture manufacturing, making vaccine production independent of chicken eggs and the potential of earlier and broader protection against infection by influenza viruses.
Biodiem was untraded at 11.5 cents.

UNILIFE MEDICAL SOLUTIONS

Unilife has posted a turnaround net profit after tax for the 12 months to June 30, 2009 of $12,806,494 compared to the previous year's loss of $8,617,238 loss.
Unilife said revenue rose 869 percent to $40,413,706 compared to $4,170,166 in the previous corresponding period "primarily due to payments received from the pharmaceutical partner" for its ready to fill syringes.
Basic earnings per share was 6.2 cents compared to a loss of 4.4 cents the previous year.
No dividend will be paid
Unilife was up 8.5 cents or 14.3 cents to 68 cents with 2.1 million shares traded.

TYRIAN DIAGNOSTICS

Tyrian says it has raised $4.98 million and eligible shareholders applied for more than half of the total shares on offer in its fully-underwritten one-for-one rights issue.
Tyrian said it received applications for 128,155,757 shares at two cents each, raising $2,563,115.
The company said the shortfall of 120,673,254 shares was expected to be placed with Patersons Securities on or about September 3, 2009.
The company said that 248,829,011 new shares and 62,207,253 attaching unlisted options would be issued.
Tyrian said the funds would assist the development and commercialization of its pipeline of diagnostic products.
Tyrian fell 0.1 cents or 5.26 percent to 1.8 cents.

CBIO

CBio hopes to raise more than $6 million for its XToll rheumatoid arthritis clinical trial and eventually list on the ASX.
CBio has previously said XToll, or recombinant chaperonin 10 (Cpn10), was a modified version of the naturally occurring protein chaperonin 10 (BD: May 28, 2008).
The company said it was intended for rheumatoid arthritis but had potential use in several autoimmune and inflammatory indications.
The trial was halted earlier this year with the company citing “impaired manufacturing capacity” (BD: Apr 3, 2009).
The Brisbane-based public unlisted company said it had appointed Novus Capital as financial adviser and underwriter to assist in the raising of capital.
The company said the $6 million target was fully underwritten by Novus and the offer was only available to sophisticated and professional investors and clients of an AFS licencee, such as financial planners and stockbrokers.
CBio said the offer would close on September 30, 2009.
The company said the funds raised would go to the current clinical trial, intellectual property development, the opening of further clinical sites and allow a scale-up manufacturing program to address the product requirements for future development projects.
CBio said it planned to restart recruitment by July 2010.
Subject to the satisfactory closing of the capital raising “and conducive market conditions” CBio said it intended to list on the Australian Securities Exchange by the end of 2009.
The company said it had always intended to consider listing but a pre-requisite was the issue of the notice of allowance of CBio’s cornerstone patent in the US and appropriate market conditions.

AVITA MEDICAL

Avita’s net loss for the 12 months to June 30, 2009 was down 58 percent to $5,128,292 on revenue up 67 percent to $3,267,427.
The revenue was primarily from sales of Recell, Breath-A-Tech and Funhaler products.
Avita said it would not pay a dividend.
Net tangible asset backing per share fell from 9.8 cents in 2007’-08 to 5.1 cents.
Diluted loss per share fell from 20.4 cents to 5.49 cents.
Avita was up one cent or 6.25 percent to 17 cents.

PHARMAUST

Pharmaust's net loss for the 12 months to June 30, 2009 was down 97 percent to $179,596 on revenue up 25 percent to $3,731,514.
The revenue was primarily from its Epichem division.
Pharmaust said it would not pay a dividend.
Net tangible asset backing per share fell from 2.5 cents in 2007'-08 to 2.3 cents.
Diluted loss per share fell from 2.74 cents to 0.07 cents.
Pharmaust was untraded at 3.5 cents.

BENITEC

Benitec says the US Patent office has allowed a patent entitled 'Multiple Promoter Expression Cassettes for Simultaneous Delivery of RNAi Agents'.
Benitec chief executive officer Sue MacLeman said the cassette was "a sequence of genetic material that links a number of RNAis together for simultaneous deliver".
"It allows you to in a single dose hit multiple points of potential resistance or mutation," Ms MacLeman.
Benitec said the patent was for an invention which provided "multiple-promoter expression cassettes for simultaneous delivery of RNAi, preferably to mammalian cells in vivo".
"There has been substantial progress with the IP prosecution and maintenance in the last 12 months," Ms MacLeman said.
"This is an extremely valuable IP portfolio in RNAi and we look forward to additional licensing and collaborations to further develop and commercialize this technology" said Ms MacLeman.
Benitec also said one of the key patents they have an option to licence from City of Hope entitled 'Ribozymes Capable of Inhibiting the Expression of the CCR5 Receptor' was granted in Japan on June 27, 2009 and would expire on March 5, 2019.
Benitec said it had the rights to more than 100 patents and patent applications either fully owned by Benitec or exclusively licenced.
Benitec has faced a series of challenges over a separate patent known as the '099 Graham patent, co-owned with the Commonwealth Scientific and Industrial Research Organisation (BD: May 26, 2009).
Benitec was up as much as 2.5 cents or 71.4 percent to six cents before closing up 1.7 cents or 48.6 percent at 5.2 cents with 12.0 million shares traded.

BIOPHARMICA

Biopharmica has appointed company secretary Deborah Ambrosini as a director.
Biopharmica said Ms Ambrosini would continue as company secretary.
Biopharmica was unchanged at 12.5 cents.