Biotech Daily

Friday November 4, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: CELLMID UP 12.5%; CATHRX DOWN 14%**

*** CLINUVEL PHASE II SCENESSE FOR EPP 'IMPROVES QUALITY OF LIFE'**

*** CBIO ACTION GROUP WINS BOARD SPILL; POISON PILL TURNS PLACEBO**

*** CYCLOPHARM 1-FOR-3.2 RIGHTS ISSUE TO RAISE $2.1m**

*** IMMURON RAISES $533k OF HOPED FOR $4.4m**

*** PHARMAUST SHARE PLAN RAISES $281k OF HOPED FOR $2.5m**

*** ONYX INCREASES, DILUTED TO 7% OF FERMISCAN**

MARKET REPORT

The Australian stock market recovered 2.62 percent on Friday November 4, 2011 with the S&P ASX 200 up 109.3 points to 4281.1 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and four were untraded.

Cellmid was the best, up 0.2 cents or 12.5 percent to 1.8 cents with 1.4 million shares traded, followed by Pharmaxis up 6.9 percent to $1.315 with 807,230 shares traded.

Allied Health and Sunshine Heart climbed five percent or more; Reva was up 3.45 percent; Impedimed, Living Cell and Resmed rose more than two percent; with Anteo, Biota, CSL, Psivida, QRX and Universal Biosensors up more than one percent.

Cathrx led the falls, down two cents or 14.3 percent to 12 cents, with 20,000 shares traded, followed by Patrys down 5.3 percent to 5.4 cents with 77,000 shares traded.

Genetic Technologies lost 3.7 percent; with Bioniche, Bionomics, Clinuvel, Cochlear, Compumedics, Mesoblast, Tissue Therapies and Viralytics down more than one percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says its 77 patient US phase II study of afamelanotide or Scenesse for erythropoietic protoporphyria has significantly improved patient quality of life.

Clinuvel said the six-month, randomized, multi-centre, double-blind, placebo-controlled study (CUV030) was primarily designed to confirm the efficacy and safety of subcutaneous, bio-resorbable afamelanotide implants in reducing the severity of phototoxic skin reactions in patients with the rare light intolerance disorder erythropoietic protoporphyria (EPP).

The company said that based on analysis of time spent outside, afamelanotide was shown to increase patients' ability to expose their skin to direct sunlight.

Clinuvel said that patients who received afamelanotide spent significantly more time in direct sunlight between the most intense hours of 10am and 3pm ($p=0.036$) and between 10am and 8pm ($p=0.025$).

The company said that patients on the drug reported a three-fold increase in the median amount of time in direct sunlight compared to placebo and many patients on the drug reported no pain or only mild pain compared to their previous life of experiencing severe phototoxic reactions.

Clinuvel said that data from an EPP-specific quality of life assessment tool showed "a dramatic improvement" from baseline for patients on the drug compared to the placebo group at 60 days ($p = 0.001$), 120 days ($p = 0.003$) and 180 days ($p < 0.001$).

The company said that safety and tolerability of afamelanotide was evaluated by measuring treatment-emergent adverse effects, which showed the drug to be safe and well-tolerated and no drug-related serious safety concerns had been identified to date in all global clinical trials, in which more than 600 patients had been treated.

The most common adverse events were associated with implant administration, such as pain or bruising following injection as well as transient nausea and headache.

Clinuvel said that a subset of patients was subjected to laboratory photo-provocation on the surface of the hand and lower back to assess the time and dose to provoke to minimal symptoms.

Of 15 patients who started the testing, only six completed the four month provocation and although a positive trend was found in the first 60 days ($p = 0.019$ to $p = 0.045$), no statistical significant result was found for days 90 or 120 when fewer patients were retested, with the reduction in participants attributed to the rigors of the testing protocol.

Clinuvel said the independent data safety monitoring board deemed afamelanotide safe for further use in man and all study centres reported positively on the afamelanotide 16mg treatment, requesting the drug for patients for compassionate use.

The company said the US Food and Drug Administration would decide whether to allow the drug to be supplied after reviewing the trial analyses.

One of the study investigators, New York's Mount Sinai School of Medicine's Prof Robert Desnick, said the study indicated efficacy in preventing severe pain from sun exposure.

"This is important for patients as it is the first treatment for EPP that will improve their now limited quality of life," Prof Desnick said.

Clinuvel chief executive officer Dr Philippe Wolgen said the trial added to the evidence that afamelanotide was effective as a prophylactic treatment for EPP, acting "as a protective umbrella for the ultra light sensitive skin of these patients".

Results from a European confirmatory phase III study (CUV029) were expected in the near future and together with data from the US study, Clinuvel plans to file Scenesse as a prophylaxis of the phototoxic symptoms of EPP before the end of 2011 for review by the European Medicines Agency.

Clinuvel fell two cents or 1.3 percent to $1.48.

CBIO

All three CBio action group proposed directors have been elected, three directors to be deposed resigned prior to the vote and other directors have not resigned as threatened.
In September, the shareholder action group called a meeting to replace chairman Stephen Jones and directors Prof John Funder and James Greig, to be replaced by former Amrad director and Avexa chair Helen Cameron, Ergon Energy chair Dr Ralph Craven and Warren Brown (BD: Sep 5, 7, 2011).
In the past two weeks, Mr Jones, Prof Funder and Mr Greig resigned from the company along with former chief executive officer Jason Yeates, (BD: Oct 26, Nov 1, 2011).
A previous 'unanimous' declaration from the board said that if any of the three action group proposed directors were elected the entire board would resign.
"The board of directors wishes to express very clearly to shareholders that all existing directors would find it untenable to work alongside any of the proposed directors and that should any of the proposed directors be voted into place, each and every existing non-executive director will resign with immediate effect," CBio told the ASX on October 21, 2011.
Ms Cameron, Dr Craven and Mr Brown were all elected with about 108 million proxy votes in favor and about 38 million proxy votes against.
A CBio media release to the ASX from recently appointed chairman Dr Michael Mansour welcomed the three elected directors and said two more directors Ross Mangelsdorf and Warren Brooks were appointed prior to the general meeting.
"We welcome Ralph Craven, Helen Cameron and Warren Brown," said Dr Mansour, who signed the unanimous declaration that none of the directors could work with any of the three action group directors, if any were elected.
"The company has experienced a significant disruption in recent weeks with the resignations of management including the executive chairman, the managing director, the finance director and the company secretary," Dr Mansour said today.
CBio said Mr Mangelsdorf was a "significant long term shareholder" in CBio, an accountant and a director of a Queensland land development company as well as an executive director and chief financial officer of Analytica.
The company said Mr Brooks was the founder and managing director of boutique financial advisory firm Clime AFM, a wholly owned subsidiary of Clime Investment Management and had 30 years experience in investment banking and stockbroking and was also a significant long term shareholder in CBio and a non-executive director of Analytica.
CBio continues with a 10-member board of directors.
CBio was up one cent or 4.4 percent to 23.5 cents.

CYCLOPHARM

Cyclopharm expects to raise about $2.1 million through a fully underwritten, non-renounceable one-for-3.2 share rights issue at four cents a share.
Cyclopharm said it would also sell existing unmarketable share parcels and offer a shortfall share facility to the rights issue.
The company said the rights issue would fund operating costs at the Cyclopet cyclotron and a US clinical trial of Technegas.
product development including its midkine program and provide working capital.
Cyclopharm said the record date was November 14, 2011, the offer would open on November 18 and close on December 2, 2011.
Cyclopharm was untraded at 3.9 cents.

IMMURON

Immuron says its non-renounceable rights issue at seven cents a share raised $532,957 of a hoped for $4,388,080.

In August, Immuron raised $516,600 in a placement at seven cents a share with one attaching option for every parcel of three new shares exercisable at 10 cents by August 31, 2012 and announced the non-renounceable one-for-five share rights issue on the same terms to raise up to $4,388,080 (BD: Aug 17, 25, 2011).

Immuron said it reserved the right to place the shortfall of 56,549,348 shares, together with attaching options.

Immuron fell two cents or 3.85 percent to five cents.

PHARMAUST

Pharmaust says its 1.8 cents a share purchase plan received valid applications for 15,591,669 shares, raising a total of $280,650.

Pharmaust said the plan was not underwritten and it would seek to place the shortfall shares.

In October, Pharmaust said it hoped to raise up to $2,521,341 for its Epichem subsidiary as well as its exploration activities and general working capital (BD: Oct 4, 2011).

Pharmaust was untraded at two cents.

FERMISCAN

Onyx Capital has increased its substantial holding in Fermiscan but has been diluted through a placement.

The change of substantial shareholder notice said the 101 Collins Street Melbourne Onyx increased and was diluted from 82,350,000,000 shares (12.5%) to 83,350,000 shares (7.22%).

Onyx said that between September 29 and October 4 2011, it sold 9,000,000 shares for $109,639 an average price of 1.2 cents a share and on October 4 acquired 10,000,000 shares for $100,000 or one cent a share.

In June, Onyx Capital increased its holding Fermiscan from 74,500,000 shares (12.8%) to 82,350,000 shares (14.1%), acquiring the 7,850,000 shares in an on-market transfer and purchase for $63,075 or an average price of 0.8 cents a share (BD: Jun 23, 2011).

Fermiscan was up 0.2 cents or 16.7 percent to 1.4 cents.