Biotech Daily

Wednesday July 15, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BONE UP 20%, NOVOGEN DOWN 12.5%**

*** CLINUVEL DRUG 'EFFECTIVE IN SOLAR URTICARIA PILOT STUDY'**

*** OCCUPATIONAL AND MEDICAL REVISES REVENUE FORECAST**

*** NEUREN INCREASES SHARE PLAN MAXIMUM**

*** IMPEDIMED RELEASES 1.2m ESCROW SHARES**

*** OBJ CONVERTS $220k NOTES TO 73.3m SHARES**

*** VIRALYTICS VOTES ON $7.5m CONVERTIBLE NOTE**

*** IMMURON SAYS 3¢ SHARE PLAN 'ATTRACTIVE'**

MARKET REPORT

The Australian stock market climbed 1.48 percent on Wednesday July 15, 2009 with the S&P ASX 200 up 57.4 points to 3,924.5 points.

Fifteen of the Biotech Daily Top 40 stocks were up, seven fell, 12 traded unchanged and six were untraded.

Bone was best, recovering some of yesterday's 50 percent loss, up two cents or 20 percent to 12 cents with 19,980 shares traded followed by Polartechnics up 10.3 percent to 7.5 cents.

Biota was up 4.9 percent to $1.49 with 1.2 million shares traded; Avexa, Genera, Phosphagenics and Tyrian climbed four percent or more; Cathrx was up 2.99 percent; Alchemia, Clinuvel, Cochlear, Heartware, Mesoblast and Universal Biosensors were up more than one percent; with Cellestis and Psivida up by less than one percent.

Novogen led the falls, down 9.5 cents or 12.5 percent to 66.5 cents with 47,841 shares traded.

Chemgenex lost 5.26 percent; Compumedics fell 3.85 percent; Optiscan, Peplin and Sirtex shed more than two percent; Acrux was down 1.35 percent; with CSL down two cents or 0.07 percent.

CLINUVEL

Clinuvel says five patients in its open-label phase II study of solar urticaria have shown increased tolerance to light following administration of afamelanotide

Clinuvel said the study conducted at Manchester Hope Hospital in the UK evaluated the efficacy of afamelanotide as a preventative photoprotectant in this disease.

The objectives of the study were to test the efficacy of subcutaneously administered afamelanotide as a photoprotective drug in patients diagnosed with solar urticaria by measuring skin reactions, characteristic 'wheal' formation and tolerance to ultra-violet light and sunlight.

Clinuvel said that following administration of a single implant of 16mg of afamelanotide subcutaneously all patients had an increase in the tolerance of skin to light of various wavelengths and intensities.

The size and intensity of skin reactions and wheal formation was significantly reduced ($p<0.003$) at 30 and 60 days following dosing of afamelanotide, the company said.

Clinuvel said the minimal urticarial dose, a measurement of tolerance to ultra-violet light and sunlight in SU, was significantly increased ($p<0.001$) in all patients at 30 and 60 days.

The company said the results indicated that afamelanotide might reduce the risk of incapacitating reactions to ultra-violet light and sunlight in solar urticaria patients.

Clinuvel's chief scientific officer Dr Hank Agersborg said the "unequivocal results give further support to the use of afamelanotide as a medicinal photo-protective drug in patients who are gravely affected by UV and sunlight".

"Clinuvel will now accelerate its program in solar urticaria worldwide and apply for permission to start phase III confirmatory controlled trials," Dr Agersborg said.

"This outcome, together with the recent interim results in our phase III program in the orphan disease erythropoietic protoporphyria, has made the chances to commercialize our drug realistic and likely," Dr Agersborg said (BD: Jan 21, 2009).

Clinuvel said solar urticaria was a skin disorder affecting about 3.5 people per 100,000 and marked by an acute allergic response following ultra-violet light or sun exposure.

Symptoms can be systemic, such as anaphylaxis, breathing difficulty, nausea and headaches, with immediate localized reactions including a characteristic 'wheal' formation and erupting flares on exposed skin sites, to swelling of soft tissues.

The company said that the available treatment was "only partially effective and consists of anti-histamines, immunotherapy and plasmapheresis or blood purification.

Clinuvel has European orphan designation to develop afamelanotide for the preventative treatment of solar urticaria.

In a 'technical note' posted on the company's website, in part warning about 'counterfeit medications' Clinuvel's chief executive officer Dr Philippe Wolgen said that when comparing the patients' response to various wavelengths of light before and after administration of afamelanotide, "all patients experienced a significant increase in skin tolerance to light and UV irradiation without any anecdotal outbreak of SU symptoms".

http://clinuvel.com/resources/pdf/asx_announcements/2009/20090715TechnicalNoteI.pdf

"The relevance of these results lies in afamelanotide's potential to offer prevention of symptoms to SU patients," Dr Wolgen said.

"We are now encouraged to evaluate afamelanotide in SU under ambient conditions in spring and summer," Dr Wolgen said.

"This trial will comprise of approximately 40 patients starting in March and ending in September 2010," he said.

"SU will be the second 'orphan' indication for which Clinuvel will apply for marketing authorization of afamelanotide," Dr Wolgen said.

Clinuvel was up half a cent or 1.6 percent to 32 cents.

OCCUPATIONAL AND MEDICAL INNOVATIONS

Occupational and Medical says revenue for 2008-'09 will be about $2.2 million, lower than previous forecasts but 26 percent above the prior financial year.
Occupational and Medical said that despite the improved revenue in the period, and strong cash-flows in the last quarter, it would remain "operating cash-flow negative" in the fourth quarter of 2008-'09 "largely due to continuing legal expenses associated with the ongoing US litigation".
Subject to audit, the company said it expected to report a loss for the financial year ended June 30, 2009 of $4.4 million to $4.6 million.
Occupational and Medical said it was "moving on opportunities to raise further equity and working capital and to attract other investment, to accelerate potential product development and revenue generating activities".
The company said product category sales improved with syringe unit sales volumes up 64.5 percent and scalpel revenue up 56 percent over the previous financial year.
Occupational & Medical said a large volume of orders in the last quarter of the fiancial year "placed temporary strain on manufacturing capacity and, as a result, delayed delivery of some stock" but the balance of stock contracted for sale during 2008-'09 would be delivered by October 2009.
The company said that although all forecast product was sold and was being delivered within customer desired delivery timetables, the impact of the slippage in delivery timing was negative in terms of revenue recognition in 2008-'09.
Occupational & Medical was unchanged at 16 cents.

NEUREN

Neuren says it can increase the maximum investment in its share plan from $10,000 worth of shares to $15,000 (BD: Jul 10, 2009).
Neuren said the ability to raise the amount was under Australian Securities & Investment Commission class order CO09/425.
The company said that the limit of $15,000 was the maximum value of shares that could be issued to a shareholder in a rolling 12 month period, so any shareholders who subscribed to the previous share plan in August 2008 would be limited to a total of $15,000 for the 12 month period.
Neuren said the ASX had also granted a waiver regarding this increase in maximum subscription.
Neuren was up 0.1 cents or 3.23 percent to 3.2 cents.

IMPEDIMED

Impedimed says 1,173,912 shares held in voluntary escrow and relating to the acquisition of Aororo Technologies will be released on July 30, 2009.
The company said a further 304,348 shares held in voluntary escrow relating to the Aororo acquisition will be released on December 31, 2009.
Following the two releases, Impedimed will have 101,236,904 shares available for trading on the ASX.
Impedimed said a further 7,510,126 shares were under ASX mandatory escrow, due for release on October 24, 2009.
When all these shares have been released from escrow, Impedimed will have 108,747,030 shares available for trading, other than employee share plan shares.
Impedimed was unchanged at 60 cents.

OBJ

OBJ says it has received conversion notices from 11 noteholders amounting to $220,000 and has issued the note-holders with 73,333,332 fully paid ordinary shares.
OBJ said the issue of the shares to the note-holders received shareholder approval at a general meeting on July 10, 2009.
OBJ was unchanged at 0.5 cents with two million shares traded.

VIRALYTICS

Viralytics shareholders will vote on a resolution supporting the company's $US6 million ($A7.55 million) convertible note facility with California's La Jolla Cove Investors.
Viralytics said its directors unanimously supported the extraordinary general meeting's sole resolution to invest the $US6 million through four convertible notes, each worth $US1.5 million.
The company said the first monthly drawdown of funds $US250,000 was received on June 15, 2009 and the company would continue to receive the monthly drawdown to a limit equivalent to approximately 15 percent of the company capital and above 15 percent is conditional on shareholder approval.
Viralytics said La Jolla had elected to convert the nominal sum of $10,000 for shares to take its place on the company's register and receive shareholder communications.
The company said it expected that the $US6 million capital injection would be sufficient to complete phase I trials and commence a commercially driven phase II clinical program.
Viralytics said an independent expert report by BDO Kendalls Corporate Finance concluded the convertible note facility was fair and reasonable to shareholders.
The meeting will be held at the Royal Automobile Club of Australia, 89 Macquarie Street, Sydney on August 21, 2009 at 10.30pm.
Viralytics was unchanged at 3.2 cents.

IMMURON

Immuron has written to shareholders notifying them that the share plan to raise up to $900,000 at three cents a share has been extended from July 14, 2009 to August 7, 2009.
Immuron said that "recent announcements may have had an adverse effect on the current share price which is below the plan price of three cents per share".
The share plan (BD: Jun 17, 2009) was announced after the non-renewal of then chief executive officer Dr Zeil Rosenberg's contract (BD: May 29, 2009), but before Dr Rosenberg claimed up to $500,000 compensation (BD: Jul 6, 2009).
Today's letter restates the support for the collaboration with Israel's Hadasit Medical Research Services and Development and the projects underway.
The letter asks investors "to review the recent announcements and also to consider the potential of our offer which we consider to be an extremely attractive offer".
Immuron was untraded at 2.7 cents.