Biotech Daily

Friday February 4, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 6%; QRX DOWN 11%**

*** WEHI SAYS IMMUNE BOOST RESPONSE MAY BE KEY TO HIV CURE**

*** PSIVIDA'S ILUVIEN SIGNIFICANT AT 33 MONTHS, BUT NOT 36 MONTHS**

*** BIONOMICS FILES PATENTS FOR MEMORY ENHANCING COMPOUNDS**

*** GSK PAYS BIOTA $1.2m RELENZA ROYALTY**

*** XCEED SELLS BORON FOR $1.5m TO WELVIC AUSTRALIA**

*** AUSTRALIAN ETHICAL TAKES 5.3% OF ATCOR**

*** LANGLEY WALKER, GROUP CEASE SUBSTANTIAL IN ACRUX**

*** ANTHONY BARTON REDUCES 2.3% IN PHYLOGICA**

*** FERMISCAN ISSUES $767k SHARE PLAN PROSPECTUS**

MARKET REPORT

The Australian stock market was up 0.87 percent on Friday February 4, 2011 with the S&P ASX 200 up 42.1 points to 4862.7 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and three were untraded.

Optiscan was the best, up 0.3 cents or 5.6 percent to 5.7 cents, with 149,120 shares traded.

Alchemia, Chemgenex, Clinuvel, Patrys and Prima climbed four percent or more; Tissue Therapies and Virax were up more than three percent; Immuron, Phylogica and Sunshine Heart rose more than two percent; with Bionomics, CSL, Impedimed, Resmed and Universal Biosensors up more than one percent.

QRX led the falls, down 15 cents or 11.1 percent to $1.20 with 35,650 shares traded.

LBT lost 6.25 percent; Benitec fell five percent; Mesoblast was down 4.55 percent; Phosphagenics, Prana and Sirtex were down three percent or more; Viralytics shed more than two percent; with Circadian down 1.45 percent.

WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its scientists have cleared an HIV-like infection from mice by boosting the function of cells vital to the immune response.

WEHI said that a team led by Dr Marc Pellegrini showed that the cell-signaling hormone interleukin-7 (IL-7) reinvigorated the immune response to chronic viral infection, allowing the host to completely clear virus.

The findings were published in the journal Cell in an article entitled 'IL-7 Engages Multiple Mechanisms to Overcome Chronic Viral Infection and Limit Organ Pathology'. An abstract is at: http://www.cell.com/abstract/S0092-8674%2811%2900012-2?switch=standard.

Dr Pellegrini said the finding could lead to a cure for chronic viral infections such as HIV, hepatitis B and C and bacterial infections such as tuberculosis, which are significant economic and global health burdens.

WEHI said that current approaches to curing chronic infections tend to focus on generating a long-lived immune response to a specific disease.

Dr Pellegrini, working with Simon Preston and Jesse Toe and Ontario Cancer Institute collaborators Prof Pamela Ohashi and Prof Tak Mak, said that long-lived immune responses to chronic diseases were not always effective and instead concentrated on how the immune response can be manipulated to better fight infection.

"Viruses such as HIV and hepatitis B and C overwhelm the immune system, leading to establishment of chronic infections that are lifelong and incurable," Dr Pellegrini said.

"Despite tremendous efforts, long-lived immune responses for some of these viruses are ineffective, because the body is so overrun by virus that the immune system, in particular T cells, just give up trying to battle the infection," Dr Pellegrini said. "Some people have coined the phrase 'immune exhaustion' to explain the phenomenon."

"Our approach is to discover some of the mechanisms that cause this immune exhaustion, and manipulate host genes to see if we can boost the natural immune response in order to beat infection," Dr Pellegrini said.

WEHI said the team investigated the role of IL-7, a naturally-occurring immune hormone, in a mouse model of HIV infection.

The Institute said IL-7 was a cytokine or a cell-signaling hormone that played a critical role in immune system development and maintenance.

"We found that IL-7 boosted the immune response in a pretty profound fashion, such that animals were able to gradually clear the virus without too much collateral tissue damage," Dr Pellegrini said, adding that that further investigations showed that, at the molecular level, IL-7 switched off the gene SOCS-3.

"In an overwhelming infection, SOCS-3 becomes highly activated and suppresses the immune response, probably as a natural precaution to prevent 'out-of-control' responses that cause collateral damage to body tissue," Dr Pellegrini said.

"In the case of these overwhelming infections, the immune system effectively slams on the brakes too early, and the infection persists," Dr Pellegrini said.

Mr Preston, who worked on the SOCS-3 studies, said that switching off the SOCS-3 gene boosted the immune system and helped the animals to completely eliminate the infection.

"The key for us was figuring out that turning off SOCS-3 only really worked when it was within T cells," Mr Preston said.

"It allowed the immune response to boost the number of virus-specific T cells and have an immune response good enough to eliminate the virus without initiating an immune response that was too large and would make the animal sick," Mr Preston said.

Dr Pellegrini said the research had provided excellent ideas for new therapies that could target and boost host immune cells to fight disease, rather than targeting the disease itself.

PSIVIDA

Psivida says data from its phase III trial of Iluvien for diabetic macular oedema shows that the drug was statistically significant at 33-months but not at 36-months.

The trial was conducted by Psivida partner Alimera Sciences, which had presented the 24-month, top-line results and had submitted a new drug application to the US Food and Drug Administration on the basis of the lower of two doses being trialed.

In December 2010, the FDA asked Alimera to provide 36-month data (BD: Jan 16, 2011).

Psivida's vice-president of investor relations Brian Leedman told Biotech Daily that the endpoint for the FDA-approved pivotal trial was significance at 24 months.

Mr Leedman said that the best result was achieved at 30-months with the lower dose of the steroid flucocinolone acetonide delivered in a 'eyelash' sized insert injected into the eye and the treatment retained statistical significance at 33-months.

Mr Leedman said the Iluvien treatment was designed to last up to 36-months and although it was not statistically significant at that point, according to the protocol, the data showed more patients reaching the defined eyesight level on the active drug than the controls, who were not receiving steroid treatment for diabetic macular oedema.

In its media release Psivida said the primary efficacy endpoint in the two part trial, was the difference in the percentage of patients whose best corrected visual acuity improved by 15 or more letters from baseline on the early treatment diabetic retinopathy study eye chart at month 24 between the treatment and control groups.

The company said that in part A of the trial, there was statistically significant therapeutic effects of 28.9 percent at month 30 (p= 0.011) and 28.4 percent at month-33 (p= 0.042) of Iluvien patients gaining 15 or more letters compared to the control group, in which fewer than 17 percent gained 15 or more letters.

Psivida said the therapeutic effect was maintained at month-36 with 28.4 percent of patients gaining 15 or more letters, but 18.9 percent of the control group gained 15 or more letters, and the p value increased to p=0.106.

Psivida said the part B trial showed similar results with statistically significant therapeutic effects of 33.9 percent at month-30 (p=0.002) and 29.6 percent at month-33 (p=0.046) of active patients gaining 15 or more letters over baseline reported compared to the control group, which had fewer than 18 percent of patients making such gains.

At month-36, 29.0 percent of Iluvien patients gained 15 or more letters compared with 18.9 percent of control patients (p=0.086).

Psivida said that by comparison, in the month-24 data earlier reported by Alimera, 26.8 percent of Iluvien patients and 14.7 percent of control patients had gained 15 or more letters (p=0.029) at month-24 in part A.

Psivida said that Alimera had reported that the combined data demonstrated a statistically significant effect at week three, maintained throughout the 36 months.

Psivida chief executive officer Dr Paul Ashton said the data was "very promising" and the company looked forward to the response from the FDA.

"If approved, Psivida will be entitled to a $US25.0 million milestone payment from Alimera and 20 percent of profits, as defined, on sales of Iluveien by Alimera," Dr Ashton said.

Psivida said the total data set included 376 patients in the Iluvien arm and 185 patients in the control arm.

Psivida said the safety data included increases in intraocular pressure to 30 millimeters of mercury (mmHg) or greater at any time point reported in 18.4 percent of patients by month-36 compared to 16.3 percent by the month-24 readout and by month-36, 4.8 percent of patients had an incisional surgical procedure to reduce elevated pressure compared to 3.7 percent of patients by month-24.

Psivida was unchanged at $4.75.

BIONOMICS

Bionomics says it has filed two patent applications covering compounds that are activators of the alpha7 nicotinic acetylcholine receptor, potentially enhancing memory.
Bionomics said activation of the alpha7 nicotinic acetylcholine receptor may also improve function in a variety of neuro-psychiatric diseases that feature memory impairment including schizophrenia, attention deficit hyperactivity disorder, as well as in mood and anxiety disorders.
The company said that the compounds covered by the patent applications exert their effects only when the natural activator of the receptor, acetylcholine, was present.
Bionomics said that the approach allowed fine-tuning of receptor activity with a broader margin of safety, enhancing the function of the receptor without unwelcome side-effects.
The company said that the prevalence of conditions where an effective, memory-improving drug could find clinical application was large, providing a very significant commercial opportunity.
Bionomics said its compounds, which showed potent activity in restoring memory in animal tests, had the potential to treat Alzheimer's disease by both improving memory and reducing brain tissue inflammation.
Bionomics' vice-president of drug discovery Dr Andrew Harvey said the company was "very excited to reach this milestone in the alpha7 program".
"The compound series described in the patents have tremendous potential for further development," Dr Harvey said.
Bionomics was up half a cent or 1.3 percent to 38 cents.

BIOTA

Biota expects to receive a royalty payment of $1.2 million from Glaxosmithkline for $17.9 million sales of Relenza in the three months to December 31, 2010.
The payment compares to a royalty payment of $2.1 million for $29.6 million in sales for the three months to September 30, 2010, a payment of $900,000 for $12.8 million sales in the three months to June 30, 2010 and the record royalty payment of $32.6 million from Glaxosmithkline for $462 million sales of Relenza in the three months to December 31, 2009.
Biota fell half a cent or 0.4 percent to $1.285.

XCEED CAPITAL

Xceed has named the Melbourne-based Welvic Australia as the buyer of its wholly-owned subsidiary Boron Molecular for $1.5 million (BD: Jan 16, 2011).
Xceed said the sale was subject to Xceed shareholder approval at a meeting to be held on February 8, 2011, with completion expected by February 15, 2011.
Xceed was untraded at 2.1 cents.

ATCOR MEDICAL

Australian Ethical's Smaller Companies Trust has become a substantial shareholder in Atcor Medical with the acquisition of 7,139,500 shares or 5.3 percent of the company.
The initial substantial shareholder notice said Australian Ethical acquired the shares for $610,395 or an average price of 8.55 cents a share between December 6, 2010 and February 2, 2011.
Atcor was unchanged at 10 cents.

ACRUX

Langley Walker and Walker Group Investments have ceased their substantial holding in Acrux.

The Sydney-based investors said they sold 1.507,830 shares at $3.55 to $3.60 a share, between December 22, 2010 and February 3, 2011.

The most recent previous notice said Langley Walker and related parties reduced their substantial holding in Acrux from 11,855,866 shares (7.44%) to 9,760,599 shares (5.90%) and the parties had acquired 2,881,388 shares in 2008 and 2009 at an average price of 89.8 cents a share with sales between 90 cents a share and $3.59 a shares.

Acrux fell one cent or 0.3 percent to $3.54.

PHYLOGICA

Anthony Barton and Associates have reduced their substantial holding in Phylogica from 28,410,323 shares (10.04%) to 21,899,031 shares (7.73%).

Phylogica was up 0.2 cents or 2.6 percent to 7.9 cents.

FERMISCAN

Fermiscan has published the prospectus for its one-for-two share rights issue at one cent a share to raise up to $767,000 (BD: Nov 23, 2010).

Fermiscan said in November 2010 that the rights issue was at the same price as a placement to raise $1 million, which was subject to shareholder approval at the company's December 1, 2010 annual general meeting.

The meeting saw the issue of 150,000,000 shares to Antus Capital defeated on proxy votes but passed "on a show of hands" and the share issue was similarly defeated by proxy votes.

Fermiscan said the funds were to complete Italian and French trials of the x-ray diffraction of hair test for breast cancer developed by Prof Veronica James, acquired by Fermiscan and subsequently sold to the SBC Research which disputes Fermiscan's ownership of the intellectual property (BD: Jan 16, 2011).

The record date is February 14, 2011, the offer opens on February 17 and closes on March 3, 2011.

Fermiscan has been in a suspension since October 28, 2009 and last traded at three cents.