



Biotech Daily

Wednesday August 25, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: CLINUVEL UP 10%; LBT DOWN 11%**
- * **DR GORAN ANDO, CBIO, XTOLL AND THE FUTURE OF PHARMA**
- * **BURNET BACKS STARPHARMA VIVAGEL SAFETY**
- * **IMPEDIMED SIGNS REIMBURSEMENT CONTRACT**
- * **CLINUVEL TRIALS SCENESSE FOR VITILIGO**
- * **PROBIOTEC PROFIT UP 6.5% TO \$9.5m; REVENUE DOWN 14% TO \$74m**
- * **COGSTATE LAUNCHES AXON SPORTS CONCUSSION PRODUCT IN US**
- * **2010 L'ORÉAL WOMEN IN SCIENCE AWARDS**

MARKET REPORT

The Australian stock market fell 1.4 percent on Wednesday August 25, 2010 with the S&P ASX 200 down 61.2 points to 4320.1 points.

Six of the Biotech Daily Top 40 stocks were up, 19 fell, four traded unchanged and 11 were untraded.

Clinuvel was best, up two cents or 10 percent to 22 cents with 326,500 shares traded.

Impedimed and Optiscan climbed more than seven percent; Alchemia was up 4.3 percent; with Psivida and Starpharma up one percent or more.

LBT led the falls, down 0.9 cents or 10.6 percent to 7.6 cents with 135,000 shares traded, followed by Novogen down 7.1 percent to 13 cents with 84,830 shares traded.

Universal Biosensors, Viralytics and Virax lost more than six percent; Phosphagenics fell 5.3 percent; Benitec, Bionomics and Prima were down more than three percent; Cellestis, Cochlear, Nanosonics, Resmed and Tissue Therapies shed two percent or more; with Acrux, Genera, Heartware and Mesoblast down one percent or more.

CBIO

Cbio director and Novo Nordisk vice-chairman Dr Goran Ando says that major pharmaceutical companies need small biotechnology companies to remain competitive. Dr Ando, a founding fellow of the American College of Rheumatology, told a Melbourne briefing at Bell Potter Securities that health costs were rising, with increasing medical needs related to ageing populations and a consequent increasing demand for new drugs. "Our reputation is at an all time low, Dr Ando said, "We are seen as profiteering from sick people, which is hard to deny. It's true, really. But we are doing more for mankind than the tobacco industry," Dr Ando said.

Dr Ando said that leading pharmaceutical companies were expected to lose between 14 percent and 41 percent of revenue by 2012 as existing drugs went off-patent and were replaced with generics. He said the companies needed two new drugs a year.

"The medical need for better treatments continues and science continues to provide novel targets," he said. "What we call one disease is actually a plethora of diseases and we can find better targeted treatments".

He said the pipeline needs of major pharmaceutical companies was "a huge opportunity for small biotechnology companies" and cited a projected rise in chronic disease rates of 62 percent for cancer from 2003 to 2023 followed by mental disorders (54%), diabetes (53%), heart disease (41%), and hypertension (39%).

He said US healthcare costs, currently at 16 percent of GDP, were expected to double between 2007 and 2016 and that meant there would have to be restrictions on reimbursement.

"You have to put some control in it. It is not a free market," Dr Ando said.

He said that personalized medicines had better responses and fewer side effects but frequently worked for one-third of the patients, had some efficacy in another one-third and no efficacy at all for the remaining one-third. He said biomarker assessments removed that risk, a positive for both patients and the public expense.

At the same time, Dr Ando said the US Food and Drug Administration was increasingly risk averse and safety focused and was "asking for an enormous amount of increased work and so the cost of producing medicines increases".

Dr Ando said that the game was changing and life cycle management of finding new indications and new formulations was not sufficient innovation to reap rewards.

He said innovation must be clinically meaningful.

Drawing the discussion to CBio, Dr Ando said biological drugs or injected large molecules were expensive compared to chemicals, with attractive efficacy, but costs were falling.

He said that formerly \$1000 a gram compounds were "one to 10 percent of the cost of 20 years ago for the same antibody".

Dr Ando said that TNF alpha antagonists had been shown not only to slow down disease progression but to stop it altogether "a revolution for patients ... but two-thirds don't respond so there is a need for more medicines".

He said XToll used a completely different mechanism of action to TNF alpha inhibitors but did not know how it worked. "Early data shows that it does seem to work".

CBio chairman Stephen Jones told the meeting that the company fell short of its initial public offering raising by \$7 million and needed that amount to complete the trial.

He said some of the money had been promised but he was hoping Bell Potter would assist in finding the balance to complete the trial and data report by July 2011.

Mr Jones said XToll was an E-coli-grown variant of Chaperonin 10, discovered at the University of Queensland to be involved in remission of auto-immune diseases in pregnant women.

CBio fell 2.5 cents or 10.2 percent to 22 cents.

[BURNET INSTITUTE, STARPHARMA](#)

The Burnet Institute says mouse studies show that Starpharma's Vivagel does not enhance HSV-2 infection, a safety hurdle for new products.

The Burnet Institute said that other candidate microbicides no longer in development had been found to enhance herpes simplex virus 2 (HSV-2) but Vivagel (SPL7013) did not.

A media release from the Burnet Institute said that the studies at Johns Hopkins University showed that SPL7013 protected against HSV-2 infection and did not increase susceptibility to HSV-2 in the mouse vaginal transmission model.

The Institute said Vivagel "provided prolonged protection against HSV-2 infection". Vivagel or a control gel was delivered vaginally to groups of 10 mice and the viral challenge was delivered later at several different times.

The viral inoculum infected 49 out of 50 control animals.

The Burnet Institute said Vivagel did not increase susceptibility to HSV-2.

Groups of 40 mice were exposed to a single dose of Vivagel and placebo gel and after 12 hours were challenged with a low dose of HSV-2 inoculum.

The Institute said that animals exposed to nonoxynol-9 and several other detergent-based candidate microbicides became more susceptible to infection for many hours after exposure reaching a peak at about 12 hours after a single exposure.

The increase in susceptibility indicated the expected increase in vaginal transmission rate for a low-dose viral inoculum.

In contrast, 12 hours after exposure to Vivagel fewer animals were infected than in the control animals, the Institute said.

Starpharma is developing SPL7013 or Vivagel to protect humans against sexually transmitted infections including HIV and herpes simplex virus 2 or genital herpes and as a treatment for bacterial vaginosis.

In studies conducted by the Burnet Institute, in collaboration with Starpharma and other partners under Starpharma's US National Institutes of Health grant, SPL7013 was found to be more active against HSV-2 and HIV than alternate dendrimer molecules tested.

These results confirmed SPL7013 as the optimal dendrimer microbicide and also demonstrated that dendrimers could be tailored to achieve optimum biological effects.

The Burnet Institute report was published in PLoS One and is available at

<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0012309>

As well as confirming SPL7013 to have the best antiviral activity against HIV and HSV-2, the Burnet Institute said that of the group of dendrimers tested, it was also shown to inhibit different strains and clinical isolates of HIV, which can infect cells via varying mechanisms.

The Institute said the broad activity had not been seen with some other candidate microbicide products in the past and the antiviral activity of SPL7013 was not affected significantly by biological fluids.

Burnet Institute chief executive officer Prof Brendan Crabb said that "for many reasons millions of women have little power to control whether or not they are exposed to sexually transmitted diseases".

"This study is an encouraging development for these women," Proff Crabb said.

Starpharma's head of development and regulatory affairs Dr Jeremy Paull said the Burnet findings "support the development of Vivagel and it is very pleasing to see how well Vivagel performs compared to other agents".

Starpharma was up half a cent or one percent to 51 cents.

IMPEDIMED

Impedimed has its first contract with a US health reimbursement company to use its L-Dex technology to aid the assessment of lymphoedema in female breast cancer patients. Impedimed said the National Preferred Provider Network (NPPN) had 3.5 million members and contracted with health insurance providers to assist doctors with reimbursement. Impedimed chief executive officer Greg Brown said that an important goal of the company's capital raising over the last 12 months was "to build our managed care team and it is gratifying to put in place our first managed care contract". Mr Brown said NPPN could provide reimbursement of L-Dex testing for its members throughout the US.

"Payment to physicians for L-Dex testing is the main driver of our business model and Impedimed looks forward to working with NPPN as we reach out to breast surgeons, surgical oncologists and cancer centers across their network to inform them of this contract," Mr Brown said.

Impedimed's US medical director Dr Walton Taylor said that networks like NPPN provided "a physician-friendly means for introducing new technologies".

Impedimed said that the National Preferred Provider Network was a preferred provider organization (PPO).

Dr Taylor said that preferred provider organizations "take on the financial risk associated with the treatment of specified groups of patients".

"These networks benefit when the cost of caring for those patients is lower than the fees they charge insurance providers for that medical coverage," Dr Taylor said.

Impedimed said the National Preferred Provider Network managed physician claims with their contracted payer clients.

Impedimed said that for the rest of 2010, physician claims would use a miscellaneous code for L-Dex testing, a specific category III code effective from January 1, 2011.

Impedimed was up five cents or 7.7 percent to 70 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says its UV-protective drug Scenesse or afamelanotide will be trialed as a repigmentation therapy for vitiligo a common disorder which caused skin to lose pigment. The company said Scenesse would be evaluated for its ability to reactivate melanin in the whitened, depigmented skin patches caused by vitiligo and that pending approval by US and EU regulators trials would begin in October.

Clinuvel chief executive officer Dr Philippe Wolgen said the vitiligo program was "a potential breakthrough for patients and testament to Clinuvel's expertise in the field of dermatology and skincare: the activation of melanin, pigment, in skin".

Clinuvel said afamelanotide mimicked the body's own response to ultraviolet light; activating melanin in the skin to protect against damage.

Clinuvel said vitiligo did not cause physical impairment but did cause significant psychological and emotional distress and affected up to two percent of the population and the most common sub-type non-segmental vitiligo affected more than 45 million people.

Clinuvel said Scenesse would be tested in a pilot non-segmental vitiligo study on its own and in combination with an existing therapy called narrowband ultraviolet B, which uses ultraviolet light to activate pigment and restore melanocytes.

The company said expected Scenesse would enhance the therapy as well as activating melanin independently by stimulating specific melanocytes in hair follicles within the skin.

Clinuvel was up two cents or 10 percent to 22 cents.

PROBIOTEC

Probiotec says its net profit after tax was up 6.5 percent to \$9,481,000 for the 12 months to June 30, 2010 on revenue down 14.1 percent to \$74,842,000.

Probiotec said its net tangible assets per share was up one percent to 79.1 cents.

The company said its would pay a fully-franked dividend of two cents per share on October 1, 2010, with a record date of September 3, 2010.

Probiotec fell two cents or 1.6 percent to \$1.24.

COGSTATE

Cogstate says it has formally launched of its joint venture with Quixote Investment, Axon Sports in the US to market and sell its sports concussion product.

Cogstate said the Computerised Cognitive Assessment Tool was designed to protect the athletic brain.

The company said that it and the Portland Oregon-based Quixote Investment each held 50 percent of the issued capital of Axon Sports and had each invested \$US500,000.

Cogstate chief executive officer Brad O'Connor said the sports concussion market was "potentially a larger market than the clinical trials market".

Cogstate was untraded at 24 cents.

2010 L'ORÉAL WOMEN IN SCIENCE AWARDS

The three winners of the L'Oréal Women in Science awards include researchers on breast cancer and malaria treatments.

The Walter and Eliza Hall Institute for Medical Research's Dr Marie-Liesse Asselin-Labat, was awarded her \$20,000 L'Oréal fellowship for work investigating the starting point of breast cancer and how breast cancer can reappear years after treatment.

The Australian National University and University of Melbourne's Dr Rowena Martin was awarded a \$20,000 L'Oréal fellowship for research into the use of existing drugs to treat malaria.

The University of Sydney's Dr Deanna D'Alessandro was awarded a \$20,000 L'Oréal fellowship for inventing ways of capturing and releasing carbon dioxide, hydrogen and other gases using molecular sponges.

A L'Oréal media release said the fellows were chosen from 160 applicants and the funds were intended to further their research and may be used for expenses, including childcare.

The company said the program was part of its "global support for women in science".