



Biotech Daily

Wednesday June 25, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECHS DOWN: LIVING CELL UP 20%, AGENIX DOWN 10.5%**
- * **LIVING CELL TRIAL SHOWS PIG INSULIN IN PATIENTS' BLOOD**
- * **PEPLIN DOSES FIRST ACTINIC KERATOSIS PATIENT**
- * **FERMISCAN CLAIMS 84% ACCURACY IN BREAST CANCER HAIR TEST**
- * **BIOPROSPECT SIGNS INSECTICIDE DEAL; LOSES M-D WARWICK DOWSE**
- * **ELLEX LOSES CEO PETER FALZON; DOWNGRADES PROFIT FORECAST**
- * **NANOSONICS LODGES TGA APPLICATION; AIMS AT CANADA, US**
- * **OMI RECEIVES FURTHER AMERICAN ORDERS; PAYMENT DELAYED**
- * **GBS VENTURES INCREASES TO 19% OF SUNSHINE HEART**
- * **NSW PLEDGES \$20m TO HIV/AIDS RESEARCH INSTITUTE**
- * **INCITIVE PLACEMENT TO RAISE \$500k**
- * **LIM SEN YAP TAKES 14% OF ARANA**
- * **GOODBYE CLINICAL CELL; G'DAY AVITA**

MARKET REPORT

The Australian stock market fell 1.0 percent on Wednesday June 25, 2008 with the All Ordinaries down 55.7 points to 5,363.1 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and three were untraded.

Living Cell was best, up five cents or 20.0 percent to 30 cents on modest volumes, followed by Heartware up 2.5 cents or 6.25 percent to 42.5 cents. Phosphagenics climbed five percent; Cochlear and Genetic Technologies rose more than two percent; with Antisense, Avexa, Circadian, Clinuvel, Pharmaxis, Prana and Universal Biosensors up more than one percent.

Agenix led the falls, down 0.4 cents or 10.53 percent to 3.4 cents, followed by Polartech down one cent or 7.14 percent to 13 cents. Alchemia and Cathrx lost more than five percent; Peplin, Tissue Therapies and Ventracor fell more than four percent; Chemgenex and Neuren were down more than three percent; Cellestis, Mesoblast and Phylogica shed more than two percent; with Acrux, Benitec, Biota, CSL, Impedimed, Novogen and Resmed down more than one percent.

LIVING CELL

Living Cell says patients in its type 1 diabetes trial had porcine insulin in their blood samples showing that Diabecell implants produce insulin and contribute to clinical benefit. Living Cell's medical director Prof Bob Elliott, said the early clinical response in the first two patients in the phase I/II trial "showed that following Diabecell treatment they were able to control their diabetes with reduced insulin dose".

Living Cell's Diabecell technology is based on the xenotransplantation of encapsulated Islets of Langerhans taken from its specialized herd of pigs bred on Auckland Island.

"By detecting porcine insulin in blood samples, we have demonstrated with certainty that the reduced insulin requirement is due to the implanted cells," Prof Elliott said.

"Porcine insulin was present in the circulation of the first patient at 11 months follow up and in the second patient six months after receiving the implant," he said.

"In the second patient it was detected after she stopped insulin injections clearly demonstrating the effect of the implants," Prof Elliott said.

Living Cell chief executive officer Dr Paul Tan said the information was consistent with the company's published research which demonstrated presence of porcine insulin in a patient 10 years after a similar implant.

"This has now been validated again after 11 months without use of immunosuppressive drugs in the current trial and at the lowest dose of Diabecell," Dr Tan said.

"The long term functioning of the encapsulated cells is important and we expect Living Cell's current encapsulation technology to keep the cells alive and functioning long term," Dr Tan said.

"The preliminary data from this world-first diabetes clinical trial of encapsulated porcine insulin-producing cells gives us increasing confidence as we advance Diabecell to larger scale trials with higher doses," Dr Tan said.

The company said earlier this month (see Biotech Daily June 5, 2008) that it would expand its Russian xeno-transplant trial.

Living Cell said that all five patients who have received transplants were well, without complication and participating in the follow-up program.

Prof Elliott will travel to Russia in July to review patients with their physicians and to collate clinical data and Living Cell expects to provide a complete update in late July.

Living Cell was up five cents or 20.0 percent to 30 cents.

PEPLIN

Peplin has treated the first patient in its dose ranging phase IIb clinical trial in patients with actinic keratosis lesions on their head including face and scalp locations.

This trial is a US and Australian multicenter, randomized, double blind, vehicle controlled clinical trial to evaluate the safety and efficacy of each of three concentrations (0.005%, 0.010% or 0.015%) of PEP005 Gel (ingenol mebutate).

Peplin said PEP005 Gel was being developed for the treatment of actinic (solar) keratosis, a pre-cancerous skin condition which can progress to skin cancer.

Sydney dermatologist and clinical trial investigator Dr Robert Rosen said the goal of therapy and in managing skin cancer was moving to address the problem of actinic keratosis lesions as early as possible and before they progress to skin cancer.

Dr Rosen said patient dissatisfaction with the current medications was "a major challenge" given long treatments, pain and persisting skin irritation and redness.

"As a result, patients are often unwilling to use their medications, particularly for lesions on the face and scalp," he said.

Peplin expects to enroll 240 patients who would apply the medication or vehicle to a 25 cm² treatment area containing four to eight lesions, once a day for either two or three consecutive days.

The primary efficacy endpoint is the complete clearance rate of lesions and the secondary efficacy endpoint will be the partial clearance rate of lesions.

Peplin will evaluate efficacy on the 57th day after treatment.

The phase IIb trial is intended to support the design of a subsequent phase III trial, which Peplin plans to begin in 2009, assuming a successful end-of-phase II meeting with the US Food and Drug Administration.

Peplin fell two cents or 4.82 percent to 39.5 cents.

FERMISCAN

Fermiscan claims an open-study of 35 women with breast cancer showed an 84 percent sensitivity for its x-ray diffraction test.

In a media release to the ASX after the market closed last night, Fermiscan said the x-ray diffraction test analyzed hair from women confirmed to have either early breast cancer or diagnosed with metastatic disease, involving the spread of cancer from the breast to other organs of the body.

Fermiscan said its test of scalp hair detected breast cancer by the presence of an additional ring in the diffraction pattern.

The study was conducted in Australia and examined four hair fibres from each patient.

The patients in the study averaged 57 years of age and were primarily Caucasian.

The study showed 27 patients had fibres which gave diffraction patterns consistent with the presence of breast cancer; five patients showed no alteration of their diffraction pattern indicative of breast cancer, and were therefore "false negatives"; and three patients were classified as indeterminate, due to damaged or abnormal fibres, and were excluded.

Including the damaged or abnormal fibres lowers the sensitivity to 77 percent.

Sensitivity is the accurate detection of patients with cancer.

Specificity is the accurate confirmation of the absence of cancer.

Early data on 800 women (see Biotech Daily; December 20, 2007) showed the Fermiscan test had 82.4 percent sensitivity and 77.2 percent specificity compared to mammography's 68 percent sensitivity and 83 percent specificity. The US National Cancer Institute website says overall sensitivity for mammography is 75 percent.

Final results for 2000 women showed the Fermiscan test had 62.5 percent sensitivity and 75.1 percent specificity (see Biotech Daily May 9, 2008).

The clinical trial's principal investigator and staff specialist oncologist at Sydney's Royal Prince Alfred Hospital Dr Jane Beith said the data was "an encouraging result for the Fermiscan technology".

Results showed no correlation with age, tumor grade or receptor expression and the consistency of the presence of the features in the diffraction pattern.

There was a non-significant trend to a negative correlation with tumor size in the early breast cancer group, that is, the smaller the tumor the more consistent was the effect.

Fermiscan said this was the first time the test had been used in a group of patients with metastatic breast disease. In the metastatic group of 18 patients there was no correlation between the consistency of the ring and age, chemotherapy or metastatic site in general. Fermiscan said neither of the two samples from patients with liver metastases gave a ring for breast cancer in any of the four fibres and the patient with brain metastases had all four fibres with a ring characteristic of breast cancer.

Fermiscan fell two cents or 2.99 percent to 65 cents.

BIOPROSPECT

Bioprospect's managing director Warwick Dowse has resigned and will leave the company in three months time.

Bioprospect said the time would allow it to identify a suitable replacement and ensure a successful handover.

The company said Mr Dowse was leaving the "for personal reasons".

Yesterday the company announced a licence agreement with the Western Australia based Bio-Gene Technology for the Qcide natural insecticide, an oil extracted from the Australian native tree, *Eucalyptus cloeziana*.

The oil contains a chemical compound called Tasmanone which has been shown to be highly effective on a broad range of insects including domestic flies, ants and animal parasites like Buffalo Fly.

Bioprospect said it granted a licence to Bio-Gene to use the existing intellectual property to develop and commercialize products containing Qcide on an international scale.

Bio-Gene will initiate development work, grow-out and extraction programs to produce the natural oil and place it into market sectors where a naturally derived and low toxicity pesticide is required.

This will cover both human and animal health market opportunities.

On commercialization, Bioprospect will receive a 2.0 percent royalty from gross sales of any product containing Qcide.

Bio-Gene will pay an initial fee of \$100,000 to Bioprospect and be responsible for all further development, intellectual property costs, agreements and product registration.

Bioprospect fell 0.2 cents or 9.52 percent to 1.9 cents.

ELLEX

Ellex Medical Lasers says chief executive officer Peter Falzon has ceased employment with the company with immediate effect.

Chief operating officer Kevin McGuinness has been appointed chief executive officer effective immediately.

Mr McGuinness joined Ellex in October 2002 as chief financial officer and company secretary and was appointed chief operating officer in April 2006 and an executive director in October 2007.

The company said that on May 2, 2008 it announced expected pre-tax earnings in 2008-'09 to grow modestly over the previous financial year, subject to the improved business performance noted at the time continuing and no further deterioration of market conditions.

Ellex said it expected pre-tax earnings to be less than the \$2.8 million reported in 2007-'08.

Mr McGuinness said that as detailed in the May announcement to the ASX, "we have experienced subdued economic conditions, particularly in the US and the uncertainty in financial markets has directly affected trading, with customers deferring purchasing decisions".

He said there was "unexpectedly strong competitive pressures" and while there was "an improvement in the performance of the company in the fourth quarter and expect to report a profit for the year and the second half, the performance has not been at a level sufficient to achieve the earnings expected at the time of the May 2, 2008 announcement".

Mr McGuinness said the result was not acceptable and the company would take steps to improve profitability.

Ellex fell 12 cents or 28.57 percent to 30 cents.

NANOSONICS

Nanosonics has submitted the conformity assessment certificate application for its ultrasound probe disinfectant with the Australian Therapeutic Goods Administration. The company said the application was a "key milestone" in the commercialization of its ultrasound probe disinfectant.

Nanosonics expects TGA approval earlier than previously advised and prior to the end of calendar year 2008.

Nanosonics said recent changes in disinfection protocols in Australia meant the product was well-positioned to become the product of choice in the Australian market.

"The accelerated approval submission will allow the company to enter the Australian market segment ahead of schedule and gain a first mover advantage through a controlled release and validation protocol, which will complement the company's global product roll-out in conjunction with its European [Conformité Européenne] CE Mark approval"

Nanosonics said. The company said it was in discussions with companies which will provide Pan-European coverage for its EU launch.

Nanosonics said Canada was an attractive market with "a strong recognition by the regulator and the market for the need for proper disinfection and standardized reprocessing of ultrasound probes". Early registration in Canada would lead to significant sales and a strong stepping stone into the lucrative US ultrasound market.

Nanosonics climbed one cent or 6.25 percent to 17 cents.

OCCUPATIONAL & MEDICAL INNOVATIONS

Occupational & Medical Innovations says it has a further order from its North American distributor for the private label version of its auto-retractable safety syringe.

Occupational & Medical said it was manufacturing to meet the order with shipment expected in July 2008.

The company said that contrary to previous advice to market, the estimated receipt of a further 25 percent of the guaranteed contractual minimum from this distributor by June 30, 2008 will not now occur, "due to slippage in the timing of receipt of orders".

Occupational & Medical said receipt of that revenue and the balance of the guaranteed contractual minimum from that distributor will occur in the 2008-'09 financial year, with the majority of the remaining commitment expected to be ordered by December 31, 2008.

The company said that "given the level of interest from potential distributors in North America" it has begun seeking the necessary regulatory approvals for sale and distribution of its auto-retractable safety syringe into the Canadian market.

Approval is expected by the end of August 2008.

Occupational & Medical said it was in advanced negotiations in relation to the appointment of three further distributors for its auto-retractable safety syringe in Australia and in markets outside the US.

Occupational & Medical was up half a cent or 2.33 percent to 22 cents.

SUNSHINE HEART

GBS Venture Partners as trustee for GBS Bioventures III has increased its substantial shareholding in Sunshine Heart from 33,333,333 shares (15.58%) to 55,986,769 shares (19.19%).

The 22,653,436 shares were bought for \$1,585,741 or seven cents a share on June 19, 2008 following the company's recent rights issue (see Biotech Daily; June 11, 2008).

Sunshine Heart was untraded at five cents.

NEW SOUTH WALES

New South Wales Premier Morris Iemma says his Government will provide \$20 million to establish a \$120 million national HIV research centre in Sydney.

Mr Iemma said the funding would help establish the National Institute for Virology which would bring 300 of the nation's top scientists working on HIV/AIDS research under the one roof.

"This work is vital to the global effort to fight this terrible disease, with 45 million people living with HIV worldwide and 16,000 new infections every day," Mr Iemma said.

He said 150 researchers were working in New South Wales as part of the National Centre in HIV Epidemiology and Clinical Research under the leadership of Prof David Cooper.

"This investment will expand the international role of our State's researchers in both the prevention of HIV and their role in emerging public health issues, such as prevention of hepatitis C," Mr Iemma said.

Mr Iemma said the National Institute of Virology would be located at St Vincent's Hospital, in Darlinghurst.

The New South Wales Minister for Science and Medical Research Verity Firth said the facility would combine academic and clinical skills.

Mr Iemma said New South Wales HIV rates had remained stable over the past decade with 404 new notifications of HIV in 2007, down slightly from 424 cases in 1997.

"These figures confirm that NSW has avoided the big rises seen in most states over the last decade," Mr Iemma said. "But we cannot afford to be complacent, one case of this disease is too many."

Prof Cooper will head the purpose-built Institute.

New South Wales said the Federal Government had been asked for matching funding, with the aim of the \$120 million development being funded one-third by Government, with the balance provided by philanthropy and the University of New South Wales on land provided by the Sisters of Charity.

The media release from the New South Wales Government said there has been "a serious long-standing interest from a major international foundation to contribute a further \$20 million to the project".

INCITIVE

Incitive has entered into an agreement with Cygnet Capital to raise \$500,000 by placing 10 million shares at five cents a share.

Incitive said Cygnet would raise the funds through a sophisticated investor placement with the shares subject to shareholder approval.

The company said the funds would be used for general working capital purposes and for the identification and review of new business opportunities.

Incitive was up half a cent or 11.11 percent to five cents.

ARANA

Lim Sen Yap and associates have increased their substantial shareholding in Arana from 29,792,439 shares (12.68%) to 32,181,701 shares (13.7%).

Lim Sen Yap is associated with Rockwell Securities of the British Virgin Islands, Alana Siew Ypa of Vaucluse Sydney, Biofusion Capital of Sydney and Siew Chin Yap and Jek Nan Yap of Malaysia.

Arana was up one cent or 0.87 percent to \$1.16.

[AVITA. CLINICAL CELL](#)

Avita Medical, formerly Clinical cell Culture which merged with Visiomed, starts trading tomorrow under its new code AVH.

Clinical Cell closed unchanged at 9.7 cents.