



Biotech Daily

Wednesday April 8, 2009

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP; BENITEC UP 24%, UNIVERSAL DOWN 9%**
- * **GENERA HPV TEST 'AS GOOD AS PAP SMEAR'; POTENTIAL LICENCE**
- * **ADMINISTRATORS 10 DAYS FROM DISCUSSING VENTRACOR DEAL**
- * **JOURNAL SAYS LIVING CELL 'PIG CELLS SAFE IN PRIMATES'**
- * **CHEMGENEX EXTENDS CAPITAL RAISING HALT TO SUSPENSION**
- * **NOVOGEN'S GLYC-101 'EFFECTIVE IN WOUND TREATMENT'**
- * **OMI EXPECTS 100% REVENUE GROWTH, CAPITAL RAISING**
- * **TELSTRA SUPER FUND TAKES 5% OF MESOBLAST**

MARKET REPORT

The Australian stock market fell 2.34 percent on Wednesday April 8, 2009 with the S&P ASX 200 down 86.8 points to 3,619.5 points.

Seventeen of the Biotech Daily Top 40 stocks were up, nine fell, three traded unchanged and 10 were untraded.

Benitec was best, up 0.6 cents or 24 percent to 3.1 cents with 100,100 shares traded.

Nanosonics and Progen climbed more than seven percent; Optiscan and Psivida were up more than six percent; Impedimed, Living Cell, Novogen and Polartech were up four percent or more; Genera and Pharmaxis climbed more than three percent; Bionomics, Circadian, Heartware and Prana rose more than two percent; with Alchemia up 1.75 percent and Arana up 0.74 percent.

Universal Biosensors led the falls, down eight cents or 9.09 percent to 80 cents with 55,000 shares traded, followed by Mesoblast down 6.25 percent to 75 cents.

Antisense lost 5.7 percent; Avexa and Clinuvel fell more than four percent; Acrux, Biota and Phosphagenics were down more than three percent; Tissue Therapies shed 2.34 percent; Resmed was down 1.8 percent; with Cellestis, Cochlear and CSL down less than one percent.

GENERA BIOSYSTEMS

Genera says a study of its Papttype human papillomavirus (HPV) test on 1,000 patients showed it was "at least as good as conventional Pap smears" in specificity.

Genera said HPV was the virus which caused cervical cancer and its test was equal to Pap smears in identifying women who were clear of cervical cancer.

Genera chief executive officer Dr Allen Bolland said in a previous 100 patient study the Papttype test was better than the Pap smear for clinical sensitivity, as demonstrated by histology.

Genera chairman Fernando Careri said the study "was carried out, at least in part, at the request of a potential licencing partner for Papttype".

The company said its Papttype worked equally well with both major cervical cytology methods, Hologic's Thinprep system and Becton Dickinson's Surepath.

Mr Careri said that the results "underlined Genera's view that Papttype was a highly competitive product".

"We wanted to demonstrate that Papttype has broad applicability across the cervical screening market, and we've certainly been able to show that," Mr Careri said.

"For the major global diagnostics companies that are considering partnering with Genera in the commercialization of Papttype, these results are expected to be significant as they confirm that Papttype would fit neatly into a range of businesses," Mr Careri said.

Gribbles Pathology's head of molecular pathology Dr Keith Byron said the results underlined his company's selection of Papttype as its HPV test of choice.

"We're very pleased with the performance characteristics of PapType," Dr Byron said.

"It's reliable, easy to use and we have great confidence in the test output", Cr Byron said.

"These results confirm that Papttype works equally well with both of the major liquid-based cytology products, as well as the more conventional cytology methods," he said.

"My view is that Papttype would be an asset to any company seeking to establish a position in the HPV testing market," he said.

Genera said the collection of de-identified clinical data was done over a two week period from 1,000 patients who had both Papttype testing and cytology and/or histology done at the same time, with the database was queried in a retrospective, sequential manner.

Genera said combined testing at the same time through Papttype and cytology or histology was the only selection criterion used in order to eliminate selection bias.

The majority of patients (83%) were identified by Papttype to be high-risk HPV negative and therefore not at risk of developing cervical cancer.

Dr Bolland said "this result correlated 98.9 percent with the results from Pap smears, which is the current preferred screening methodology around the world".

Genera said it expected to release further clinical data in the current quarter, which will be the basis for its European and Australian regulatory submissions.

Genera was up 1.5 cents or 3.75 percent to 41.5 cents.

VENTRACOR

Administrators Ferrier Hodgson say that they are in discussions with several companies over the sale of Ventracor's assets, but can't say anything for eight to 10 days.

Ferrier Hodgson spokesman Michael Cave told Biotech Daily that administrator Steven Sherman had met with Ventracor investors in Sydney yesterday.

Mr Cave said there was not much able to be disclosed, but Ferrier Hodgson expected to know more about a potential sale in "eight to 10 days".

He said the administrators were in discussions with "a number of parties".

Ventracor is in a voluntary suspension and last traded at 8.3 cents.

LIVING CELL TECHNOLOGIES

Living Cell says the safety of using pig cells as a method of treatment has been supported by leading virologists in an independent scientific paper.

Living Cell said the report, published in the journal 'Xenotransplantation' said that even large doses of pig retroviruses injected into monkeys did not cause infection or disease. The report, entitled 'No in vivo infection of triple immunosuppressed non-human primates after inoculation with high titres of porcine endogenous retroviruses' was published in the January edition of Xenotransplantation (Jan;16 (1): 34-44).

The company's Diabecell product for Type 1 diabetes is comprised of encapsulated porcine islets of Langerhans or insulin-producing pig cells.

Living Cell said Diabecell was in clinical trials for the treatment of type 1 diabetes without the use of immunosuppressive drugs.

The company's medical director Prof Bob Elliott said the report "goes a long way to eliminating concerns that endogenous retroviruses from pig cells would infect people who receive pig cell transplants".

Living Cell said "large amounts of live viruses and viruses modified to infect human cells in culture were injected into monkeys and baboons without causing disease".

"The animals were given three different immunosuppressive drugs to weaken their immune system and exposure to significant amounts of these viruses still did not result in retroviral infection as no proviral DNA was found integrated in recipient cells or organs after 11 months," Living Cell said.

The company said Diabecell was given without immunosuppressive drugs so patients retained a healthy immune system and its pigs did not secrete infectious virus and were tested regularly to be free of other viruses, bacteria and parasites.

Living Cell's chief executive officer Dr Paul Tan said the report was consistent with his experience with providing pig cell implants for 18 patients under previous regulations, with "no evidence of pig transmitted infections up to nine years following the implants".

"The risk of pig retroviral infection has always been theoretical as it has never occurred," Dr Tan said.

"This new report shows that infection does not occur even in monkeys made susceptible to infection," Dr Tan said.

The paper published in the most recent issue of Xenotransplantation describes a study with rhesus monkeys, pig-tailed monkeys and baboons that were given the immunosuppressant drugs cyclosporine A, methylprednisolone and the rapamycin derivative to induce a state of chronic immunosuppression.

Living Cell said that before inoculation with porcine endogenous retroviruses, complement activation was blocked with C1 esterase inhibitor.

The company said the report's authors concluded that "neither the inoculation of cell-free nor cell-associated [porcine endogenous retroviruses] using a virus already adapted to primate cells results in an infection; this is despite the fact that peripheral blood mononuclear cells of the same animals are infectible in vitro."

Living Cell climbed half a cent or 4.35 percent to 12 cents.

CHEMGENEX

Chemgenex has requested a suspension to follow on from the trading halt requested on April 6, 2009 relating to a capital raising.

Chemgenex last traded at 52 cents.

NOVOGEN

Novogen says its 81 percent subsidiary, Glycotex Inc, has shown statistical significance for GLYC-101 for eyelid wound closure.

Novogen said the interim analysis was in a phase II study evaluating the effect of the GLYC-101 gel on complete wound closure and cosmetic outcomes in cosmetic surgery patients undergoing carbon dioxide laser skin resurfacing on the lower eyelid area.

The company said the analysis was conducted after 26 subjects completed the study.

Novogen said efficacy outcomes were statistically significantly in comparing GLYC-101 (0.1%) and GLYC-101 (1.0%) to placebo with p-values of 0.0062 and 0.0331, respectively.

The interim results suggested that the time to wound closure would be shorter for eyelids treated on the active arms when compared to placebo in the final analysis.

Novogen said the assessment of safety data was ongoing.

The phase II randomized, double-blind, placebo-controlled clinical study will continue enrolment to about 48 patients at one clinical trial site in Beverly Hills, California.

Novogen said the gel was applied on one lower eyelid and a different test article on the other lower eyelid applied topically to the laser-ablated area immediately following the laser procedure and for four consecutive days for a total of five applications.

The primary efficacy endpoint of the study is time to complete wound healing and the secondary efficacy point is cosmetic outcomes, including scarring.

The study is observing the effects of the topical agent over the course of one month following the initial treatment with the GLYC-101 gel or placebo.

Novogen said GLYC -101 was being developed to stimulate and modulate the natural cascade of wound healing of several cell populations and potential applications included wound healing after laser ablation, burns, surgical wounds, venous and diabetic ulcers.

Novogen was up 2.5 cents or 4.85 percent to 54 cents.

OCCUPATIONAL & MEDICAL INNOVATIONS

Occupational & Medical says it expects a 100 percent growth in revenue to \$3.2 million for the 2008-'09 financial year.

Occupational & Medical said the revenue update was on the basis of sales of its auto-retractable safety syringe, safety scalpel and associated revenue through existing sales channels and commitments.

The company said the growth illustrated its "initial and increasing market penetration success of its safety engineered medical devices.

Occupational & Medical said the April 6, 2009 Cardinal Health agreement provided for fixed revenue under the new contract to June 30, 2009, with estimated revenues thereafter linked to rolling quarterly forecasts for the rest of the new agreement term.

The company said all its other distributors were "continuing to perform satisfactorily towards current distribution targets previously announced".

Occupational & Medical chief executive officer Matthew Austin said the company would "report a loss for the current financial year, however this projected doubling of top-line revenue reflects OMI's ability to engage and adapt to the market to ensure the long term success of our product portfolio".

Occupational & Medical said that "to accelerate potential product development and revenue generating activities, the directors confirm previous advice that further capital raising initiatives will be activated in the near term".

Occupational & Medical was up two cents or 8.7 percent to 25 cents.

MESOBLAST

Telstra Superannuation Fund has become a substantial shareholder in Mesoblast with a holding of 6,852,441 shares or 5.04 percent of the company.

Telstra Super said it became substantial on April 2, 2009, when it acquired 1,622,378 shares at 72 cents a share, which was the price of the placement announced on March 30, 2009.

Mesoblast fell five cents or 6.25 percent to 75 cents.