



Biotech Daily

Tuesday May 4, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: CLINUVEL UP 7%; SUNSHINE HEART DOWN 12%**
- * **TWO STUDIES BACK ELLEX'S 2RT RETINA REGENERATION THERAPY**
- * **SBC RESEARCH BUYS FERMISCAN IP FOR \$250k**
- * **IMMURON BEGINS PRECLINICAL INFLUENZA TRIALS**
- * **KINETIC INCREASES TO 6.1% OF NANOSONICS**
- * **BIOMD IN 3rd PARTY FEASIBILITY STUDY**
- * **ANTISENSE ATL1101, ATL1103 READY FOR PHASE I TRIALS**
- * **QUEENSLAND GRANTS ALCHEMIA \$1m FOR OPIOID SIDE EFFECTS**
- * **ACUVAX 1-FOR-1 RIGHTS ISSUE TO RAISE UP TO \$3.3m**
- * **HEARTWARE Q1 REVENUE UP 613% TO \$12m**
- * **XCEED CAPITAL EGM DIRECTOR OPTIONS VOTE SPLITS 63:37**

MARKET REPORT

The Australian stock market fell 1.01 percent on Tuesday May 4, 2010 with the S&P ASX 200 down 48.4 points to 4737.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and seven were untraded.

Clinuvel was best, up 1.5 cents or 6.7 percent to 24 cents with 691,051 shares traded followed by Antisense up 5.9 percent to 1.8 cents with 1.3 million shares traded. Bionomics, Genetic Technologies and Psivida climbed more than four percent; CSL and Pharmaxis rose more than two percent; with Acrux, Chemgenex, Cochlear, Living Cell, QRX and Starpharma up more than one percent.

Sunshine Heart led the falls, down 0.4 cents or 11.8 percent to three cents with 320,000 shares traded followed by Viralytics down half a cent or 10.9 percent to 4.1 cents with 1.8 million shares traded. Phosphagenics lost 7.1 percent; Sirtex was down 6.9 percent; Biota, LBT, Prana and Prima fell more than five percent; Tissue Therapies was down 4.9 percent; Cellestis was down 3.3 percent; with Circadian and Optiscan down more than one percent.

ELLEX MEDICAL LASERS

Ellex says initial clinical results of two studies supporting the company's Retina Regeneration Therapy (Ellex 2RT) are being presented in Florida.

The presentations are being presented at the Association for Research in Vision and Ophthalmology's annual meeting, May 2-6, 2010, in Fort Lauderdale and detail the efficacy of Ellex 2RT for the treatment of age-related macular degeneration (AMD) and diabetic retinopathy - two leading causes of blindness in the developed world.

The poster entitled 'Novel Nanosecond Laser Treatment To Prevent Vision Loss From Age-related Macular Degeneration' reported a trial of 20 patients each treated in one eye. "Seven eyes had been tested at six months post laser and a large number of treated eyes, and untreated eyes were showing some signs of overall retinal function improvement," the poster concluded.

"The dramatic effect seen in some subject's fellow eye was not expected," the poster reported.

"We aim to treat 50 high risk eyes over the next year to complete the pilot study," the poster said.

"It is anticipated that the 2RT laser will address the underlying cause of [age-related diabetic oedema] which appears to be reduced flux across Bruch's membrane," the poster concluded.

"The laser design should enable the positive features of previous laser studies for early [age-related diabetic oedema] to be harnessed without entertaining any of the negative effects such as neovascularization," the poster said.

The abstracts are at <http://www.abstractsonline.com/plan/start.aspx>

The '2RT for Early AMD' study is being undertaken in partnership with the Centre for Eye Research Australia and the Royal Victorian Eye and Ear Hospital, led by the Centre for Eye Research's head of macular research Prof Robyn Guymer.

"Currently, when a patient is diagnosed with early AMD, they're told that nothing can be done until the disease reaches its late stages, by which time some patients have suffered irreversible vision loss," Prof Guymer said.

"With Ellex 2RT, we hope to halt, or partially reverse, the progression of AMD before it threatens a patient's sight," Prof Guymer said.

Prof Guymer presented the initial six month study results on May 2, 2010.

The '2RT for Proliferative Diabetic Retinopathy' study is being conducted at several study sites in Australia under principal investigator Prof Robert Casson.

The clinical prospective, double-blind, comparative investigation aims to compare the efficacy of Ellex 2RT with retinal laser photocoagulation for the treatment of diabetic retinopathy.

Prof Casson is expected to present the completed six month study on May 6, 2010.

The presentation is entitled 'A Pilot, Prospective, Randomized Clinical Trial of a New Nanopulse Retinal Laser versus Conventional Photocoagulation for the Treatment of Diabetic Macular Oedema'.

The study investigated 22 patients in the 2RT group and 18 in the control group.

The poster said that the safety profile of 2RT was excellent and the study concluded that after three months of follow-up "2RT was safe and at least as clinically effective in the treatment of [diabetic macular oedema] as conventional laser".

"Given the potentially greater safety profile of 2RT compared to photocoagulation and the ability to treat oedema closer to the fovea, this new laser modality warrants further evaluation in a larger study," the study said.

Ellex climbed 3.5 cents or 29.2 percent to 15.5 cents with 20.911 shares traded.

FERMISCAN

Fermiscan's administrators Woodgate & Co have sold the company's intellectual property and other assets to the Sydney Breast Clinic-related company SBC Research.

The Clinic's managing director Ron Phillips told Biotech Daily that people associated with the Sydney Breast Clinic held a minority share of SBC Research.

Mr Phillips said that no one associated with Fermiscan was involved in SBC Research. Fermiscan's core intellectual property is the x-ray diffraction of hair test it acquired from the inventor Prof Veronica James.

Woodgate & Co said that a number of offers to purchase the assets or invest in the company were considered and the intellectual property and certain assets were sold for \$250,000 plus GST to SBC Research, which had been settled.

Fermiscan raised and spent tens of millions of dollars to study the test.

Mr Phillips said the SBC Research group believed that the x-ray diffraction of hair test for breast cancer had some merit and a rigorous independent examination of the test would be undertaken to determine its accuracy.

Fermiscan failed to merge with Polartech and embarked on litigation against Prof James, which it lost.

Fermiscan bought the Sydney Breast Clinic in 2008 for \$5.5 million but sold it in 2009 for \$1 million (BD: Oct 2, 2009).

Major shareholder Leon Carr was an executive of Fermiscan and for a short period of time was a director of the company.

In December 2009 Mr Carr was described as "dishonest" by a New South Wales Supreme Court judge and the matter - unrelated to Fermiscan - was referred to the Australian Securities and Investments Commission (BD: Dec 16, 2009).

IMMURON

Immuron says it has approval to begin pre-clinical trials in ferrets for its influenza prevention antibodies.

Immuron said the trials at the Commonwealth Scientific and Industrial Research Organisation Australian Animal Health Laboratory in Geelong were expected to start within two months and follows successful mouse model work (BD: Aug 4, 2010).

The company said a series of placebo controlled experiments would test the efficacy of the cow colostrum based product as a human influenza preventative.

Immuron said the first indicative results were expected by August 2010.

Immuron chief executive officer Dr Grant Rawlin said that success in the ferret model was "acknowledged as highly significant by both international regulatory authorities and potential business partners as an indication of future success in the human clinical setting".

"If these trials are successful the company intends to start clinical trials in humans this year," Dr Rawlin said.

Immuron was up 0.1 cents or 1.6 percent to 6.5 cents.

NANOSONICS

Kinetic Investment Partners has increased its substantial shareholding in Nanosonics from 11,339,591 shares (5.04%) to 13,729,317 shares (6.10%).

Kinetic is part of Challenger Financial Services and its principals are Jonathan Findlay, Richard Sharp and Anthony Porto.

Nanosonics was up half a cent or 0.9 percent to 58.5 cents.

BIOMD

Biomd says with its subsidiary Celxcel it has signed a feasibility study with an unnamed tissue heart valve company.

Biomd said the parties would use certain elements of Biomd's Adapt tissue engineering technology to enhance the manufacturing and performance of one of the unnamed company's existing US Food and Drug Administration-approved tissue heart valves.

Biomd said the study did not prevent Celxcel from partnering in similar studies with other heart valve companies.

The company said the global market for tissue heart valves was estimated to be \$US700 million and growing at seven percent per year.

Biomd was untraded at 3.1 cents.

ANTISENSE THERAPEUTICS

Antisense says it is concluding its relationship with Israel's Teva Pharmaceuticals over ATL1102 for multiple sclerosis and has two other compounds ready for phase I trials.

In a "business update" to shareholders Antisense said it applied for a new patent for ATL1102, specifically for multiple sclerosis in 2009.

Antisense said that Teva had also returned the rights to the aerosol or inhaled application of ATL1102 which would add another project to its pipeline.

Antisense said that based on successful animal studies, the inhaled ATL1102 had significant potential as a treatment for asthma.

Following Teva's ending of the licence agreement (BD: Mar 24, 2010) Antisense said it had retrieved its data and was negotiating the use of data generated by Teva.

Antisense said it would then have a complete package of data and intellectual property rights "to support the potential further development of the drug and possible out-licensing to a partner".

Antisense said ATL1103 for abnormal growth and sight disorders and ATL1101 for prostate cancer were developed to the stage where they could begin first in human clinical trials.

Antisense was up 0.1 cents or 5.9 percent to 1.8 cents with 1.3 million shares traded.

ALCHEMIA

Queensland Premier Anna Bligh has awarded Alchemia a \$1 million grant to support the discovery of novel opioid-mediated therapeutics with reduced side effects for severe pain. Alchemia said the research-industry partnership program grant supported the continuation of an existing collaboration with the University of Queensland Pain Laboratory's Prof Maree Smith.

The company said the collaboration would "investigate the feasibility of separating the desired analgesic activity of opioid pain killers from the severe side effects that are associated with this class of drugs".

Alchemia chief executive officer Dr Pete Smith said the grant would help the company "further validate and apply our Vast discovery platform through innovative collaborations with selected leaders in the field".

Alchemia said preliminary research with Prof Smith identified molecules that provided the first indication that potent analgesia could be achieved without constipation.

Alchemia said the research would assist understanding the mechanisms of opioid analgesia and pharmacology and support the development of improved therapies.

Alchemia was unchanged at 53.5 cents.

ACUVAX

Acuvax hopes to raise up to \$3.3 million through a one-for-one non-renounceable share rights offer at half a cent per share.

Acuvax said it would issue up to 661,245,584 shares in the rights issue.

The company said the proceeds would be used primarily to provide working capital to pursue its immediate commercial objectives, of securing total funding of up to \$10 million to acquire a majority shareholding in Hawaii Biotech and pursue opportunities in areas of technical innovation in the company's core competency of recombinant technologies and other opportunities.

Acuvax said the record date was May 12, 2010, the opening date was May 14 and the closing date was May 27, 2010.

Acuvax fell half a cent or 38.5 percent to 0.8 cents with 2.1 million shares traded.

HEARTWARE INTERNATIONAL

Heartware says it has received revenues of \$US10.7 million (\$A11.6m) for the three months to March 31, 2010 compared to \$US1.5 million in the first quarter of 2009.

Heartware's chief executive officer Doug Godshall said the first quarter results reflected "the continued commercial expansion in markets outside of the United States, which accounted for approximately 75 percent of our revenues for the quarter".

"As noted previously, revenues in the US were paused during the first quarter, as enrollment in our bridge-to-transplant clinical study was completed in late February," Mr Godshall said.

"Last week, we resumed implanting patients in the US, following approval of a continued access protocol by the Food and Drug Administration for the bridge-to-transplant study," he said.

Heartware said the net loss for the first quarter of 2010 was \$US4.5 million, or a US 35 cents loss per basic and diluted share, compared to a \$US6.2 million net loss, or a loss of US 70 cents per basic and diluted share, in the first quarter of 2009.

Heartware was up one cent or 0.6 percent to \$1.69.

XCEED CAPITAL

A resolution on the issue of 10,000,000 options to Xceed's George Cameron-Dow was passed with 54,068,834 proxy votes in favor (63.3%) and 31,282,916 proxy votes against (36.7%).

Xceed was untraded at 1.2 cents.