



# Biotech Daily

Thursday July 17, 2008

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECHS UP: BIONOMICS UP 10%, UNIVERSAL BIO DOWN 6%**
- \* **MEDIMMUNE EVALUATES NORWOOD VIROSOMAL VACCINE**
- \* **HALCYGEN COMPLETES PHASE III SUBA-ITRACONAZOLE DOSING**
- \* **VIRALYTICS UNVEILS ITS NEW DIRECTIONS**
- \* **SIX PRANA SCIENTISTS TAKE PBT2 TO CHICAGO CONFERENCE**
- \* **LIVING CELL HOSTS DIABETES CONFERENCE**
- \* **BRAINZ DIRECTOR DR ROBIN COSGREVE RESIGNS**
- \* **FMR FIDELITY CORRECT HEARTWARE HOLDING**

## MARKET REPORT

The Australian All Ordinaries Index climbed 29.9 points on Thursday July 17, 2008 up 0.6 percent at 4,977.4 points.

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

Bionomics was best, up three cents or 10.0 percent to 33 cents on small volumes following an investor broadcast; followed by Starpharma up 2.5 cents or 9.09 percent to 30 cents.

Biota climbed 6.8 percent; Neuren was up 5.26 percent; Arana, Cochlear and CSL were up more than three percent; Acrux, Pharmaxis, Progen and Ventracor rose more than two percent; with Viralytics up 1.67 percent.

Universal Biosensors led the falls, down five cents or 6.25 percent to 75 cents, followed by Phylogica down half a cent or 5.56 percent to 8.5 cents.

Chemgenex lost 4.12 percent; Antisense and Novogen were down more than three percent; Living Cell shed 2.04 percent; with Prana down 1.1 percent.

## NORWOOD IMMUNOLOGY, NORWOOD ABBEY, ASTRAZENECA

Astrazeneca's Medimmune will evaluate the virosomal vaccine technology for respiratory syncytial virus developed by Norwood Immunology's Virosomal Biological.

Medimmune is 100 percent owned by the Astrazeneca Group and Virosomal Biological is a wholly-owned subsidiary of Norwood Immunology.

Norwood Immunology chief scientific officer Prof Richard Boyd told Biotech Daily that Medimmune would pay an "undisclosed sum" for the rights to the virosomal vaccine. He said a virosome was a virus with the genetic material removed.

"Virosomes are produced in a highly active form supercharged with immune-enhancing molecules giving up to 150-fold response compared to other treatments," Prof Boyd said. Prof Boyd said virosomal vaccines were a platform technology and Medimmune was specifically investigating its use for respiratory syncytial virus.

In a media release to the ASX from Norwood Abbey, Norwood Immunology said it had agreed to an exclusive collaboration period with Medimmune of six months in exchange for an exclusivity fee and the reimbursement of costs associated with performing collaborative research programs using Medimmune vaccine candidates and the group's virosome technology.

Norwood Immunology chief executive officer Richard Williams said the agreement was indicative of the attractiveness of the Virosomal Biological's adjuvanted virosome technology to major vaccine partners.

"We look to build on this second vaccine partnership with a major pharmaceutical company and anticipate seeking partners for our preclinical package for herpes simplex virus in the second half of 2008," Mr Williams said.

The publicly listed Norwood Abbey holds 48.6 million shares or 21 percent of the unlisted Norwood Immunology.

Norwood Abbey was up 0.1 cents or 6.25 percent to 1.7 cents.

## HALCYGEN

Halcygen says recruitment and dosing in three pivotal pharmacokinetic studies for Suba-itraconazole have been completed.

The company said its strategy for US Food and Drug Administration approval for Suba-itraconazole under an investigational new drug application was to compare it to the market's leading product, Sporanox.

Halcygen said the pharmacokinetic studies would examine the absorption, distribution, metabolism and excretion of the drug.

Halcygen's chief executive officer Dr Roger Aston said the company had completed recruitment and treatments in the first four-way crossover study "within a month of IND approval".

"So we are well on track with our registration program," Dr Aston said.

"Initiation of pivotal studies in the US is an important milestone for Halcygen," he said. Halcygen said it had clinically evaluated Suba-itraconazole "in five successful pharmacokinetic studies in Australia".

The company said these studies demonstrated that Suba-itraconazole had significantly improved bioavailability or absorption by the gastrointestinal track compared with the market leader, enabling the use of a lower dose of the drug. Halcygen said Suba-itraconazole gave more stable blood levels compared to Sporanox.

Halcygen said it was targeting the global market for itraconazole of more than \$US600 million a year.

Halcygen was untraded at 30 cents.

## VIRALYTICS

Viralytics executive chairman Bryan Dulhunty and founding inventor and director Prof Darren Shafren have begun a series of investor and analyst meetings.

In Melbourne, Mr Dulhunty told Biotech Daily that they would be talking to brokers and the industry media about the company's new direction and a new clinical trial.

Mr Dulhunty said the company had been through an extensive restructure and the share register had completely changed from the Viralytics of several years ago that was then intertwined with the public, unlisted, Queensland based-CBio.

He said the company's top 40 shareholders held less than 35 percent of the stock with the top two, the University of Newcastle holding 4.8 percent and Scicapital 4.6 percent.

Mr Dulhunty said Viralytics holding in CBio had been diluted from six percent to four percent, but said it remained an excellent investment.

He said Viralytics needed a cornerstone investor to take 15 to 20 percent and there was space on the board for two more directors with the right qualifications.

Mr Dulhunty said the company had a cash burn of \$2.8 million a year with cash in the bank of \$2.8 million which would see it through further talks with the US Food and Drug Administration and continue the two existing phase I Cavatak trials.

Prof Shafren said there were more than 100 enteroviruses with more than 20 variants of the coxsackie A virus and Cavatak was the wild type coxsackie A21 virus.

He said the shape allowed it to bind to other cells and at the University of Newcastle "noted a marked cytotoxic effect on melanoma cells".

Prof Shafren is a professor of virology at the University of Newcastle.

Viralytics acquired the intellectual property covering the use of coxsackieviruses from the University in 2006.

Mr Dulhunty said that after reaching registration and the market the company expected to have about 15 years of patent protection.

US patents cover the use of four coxsackie A viruses for the killing of cancer cells and the European patents cover all coxsackie A viruses for the killing of cancer cells.

Prof Shafren said there appeared to be 90 percent in vitro efficacy against melanoma cells and 50 to 60 percent efficacy against breast and prostate cancer cells.

The company is also investigating Cavatak's potential against ovarian, multi-myeloma, glioma and head and neck cancers.

It has two dose-escalating phase I trials of Cavatak, an intra-tumoral trial for late stage melanoma and an intravenous trial for late stage melanoma, breast and prostate cancer.

Prof Shafren said Viralytics was the only Australian public company working on oncolytic viruses, with "about a dozen worldwide".

"Some are working on wild type viruses and some on genetically modified viruses," Prof Shafren said.

"No one has done a deal on oncolytic viruses except Onyx 015," he said.

Prof Shafren said it was taken over and a phase III trial was cancelled. A Chinese company genetically altered the drug and has taken it to market in that country.

Mr Dulhunty said there were 10 to 12 competitors working with other viruses with some in phase II and one in phase III, but he was confident that Cavatak was superior and the others would "ease the regulatory burden".

"The perfect virus replicates quickly, has low levels of previous exposures and has a low pathogenicity to humans," Prof Shafren said.

"We believe our virus has those three and is as good as, or better than, others in clinical trials," Prof Shafren said.

Mr Dulhunty said early trial results were "very encouraging".

Viralytics was up 0.1 cents or 1.67 percent to 6.1 cents.

## PRANA

Prana says further results from its phase IIa clinical trial of PBT2 for Alzheimer's disease will be presented at a conference on Alzheimer's in Chicago.

Prana's chairman of its research and development advisory board Dr Jeffrey Cummings will give a talk in the 'Hot Topics' section at the International Conference on Alzheimer's Disease in Chicago on July 30, 2008.

Dr Cummings talk is entitled 'Targeting abeta [amyloid beta] as a modifying therapy of Alzheimer's disease: safety, efficacy and biomarker findings of a phase IIa randomized, double-blind placebo-controlled trial of PBT2'.

Prana's executive chairman Geoffrey Kempler told Biotech Daily the presentation would build on the earlier ASX-announcement of early trial results (see Biotech Daily; Feb 26, 2008).

As well as Dr Cummings, Prana said five of its scientists and consultants would present their research at the International Conference on Alzheimer's Disease (ICAD) and discuss PBT2.

Mr Kempler said amyloid beta required metals in order to become toxic in the brain and PBT2 protected the brain from this interaction."

"We are increasingly optimistic about the prospects of PBT2 as a therapy for Alzheimer's disease, and our inclusion in Hot Topics and the associated Alzheimer's Association Press Briefing at ICAD is indeed very gratifying" said Mr Kempler.

Prana fell half a cent or 1.1 percent to 45 cents.

## LIVING CELL

Living Cell has attracted leading scientists and specialists to a New Zealand seminar on porcine islet transplants for type 1 diabetes.

Living Cell said the experts coming to August 8, 2008 seminar include Canada's Robarts Institute Prof David White, the University of Alberta's Prof Gregory Korbutt Moscow's Sklifosovsky Institute's, Prof Nikolai Skaletsky, the University of Perugia's Prof Riccardo Calafiore and the University of Glasgow's Dr Linda Scobie.

Living Cell's medical director Prof Bob Elliott said he was "delighted to have so many islet implant experts participating".

Prof Elliot said the topics covered will include the health status of the pigs whose insulin producing cells are implanted into humans, the absence of immuno-suppression drugs, early clinical data from human studies and post transplant monitoring.

"The early results that have been obtained to date from Living Cell porcine islet implants have been extremely encouraging," Prof Elliott said.

"I look forward to discussing the results with fellow scientists and practitioners who see the importance of islet cell treatment and are keen to advance this technology rapidly for the benefit of people with insulin dependent type 1 diabetes," Prof Elliot said.

Living Cell fell half a cent or 2.04 percent to 24 cents.

## BRAINZ

Brainz says that Dr Robin Congreve has resigned as a director of the company.

Dr Congreve is the chairman of Neuren.

Brainz was untraded at 1.7 cents.

## HEARTWARE

The US based FMR Corp and Fidelity Investments has corrected its substantial shareholder notice for Heartware (see Biotech Daily; July 15, 2008)

On July 15 FMR Corp and Fidelity Investments said it held 22,636,983 shares or 9.12 percent of the company.

Today the company said the holding was 7.29 percent of Heartware. The latter percentage includes the 62,256,562 shares issued following the recent \$31 million placement (see Biotech Daily; May 23 2008).

Heartware has a total of 310,356,839 shares on offer.

Heartware was untraded at 45 cents.