



Biotech Daily

Thursday December 11, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECHS DOWN: POLARTECH UP 28%, VENTRACOR DOWN 48%**
- * **INVESTORS SHUN VENTRACOR; CASH TO MARCH 2009**
- * **ARANA BEGINS ART621 PHASE II RHEUMATOID ARTHRITIS TRIAL**
- * **CSL'S DR ANDREW CUTHBERTSON DETAILS R&D PIPELINE**
- * **CIRCADIAN, CSL, CANCER COUNCIL SPONSOR LORNE CONFERENCE**
- * **HEALTHLINX OVARIAN CANCER TEST 10-YEAR UK DISTRIBUTION DEAL**
- * **VIRAX VACCINATES 1st HIV PARTICIPANT**
- * **LIVING CELL: NEUROTROPHIN CELL EFFECTIVE IN PARKINSON'S MODEL**
- * **NOMINATIONS OPEN FOR VICTORIA PREMIER'S RESEARCH AWARD**

MARKET REPORT

The Australian stock market fell 1.1 percent on Thursday December 11, 2008 with the All Ordinaries down 39.1 points to 3,534.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and eight were untraded.

Polartech was best for the second day in a row, closing up 2.6 cents or 27.66 percent to 12 cents with 1.4 million shares traded, followed by Labtech up 25.81 percent to 19.5 cents, Living Cell up 23.81 percent to 13 cents and Acrux up 20.43 percent to 56 cents.

Neuren climbed 12 percent; Circadian was up 8.33 percent; Chemgenex was up 6.38 percent; Antisense and Progen rose more than two percent; with Sirtex up more than one percent and Arana and Pharmaxis up by less than one percent.

Ventracor led the falls, down 3.5 cents or 47.95 percent to 3.8 cents with 9.7 million shares traded, followed by Viralytics down 25 percent to three cents and Bionomics down 14.29 percent to 18 cents,

Optiscan and Phylogica lost more than 10 percent; Genetic Technologies fell 9.52 percent; Phosphagenics was down 8.14 percent; Benitec, Clinuvel, Cochlear and Psivida lost more than six percent; Avexa and CSL fell more than four percent; Cellestis shed 2.6 percent; with Alchemia and Resmed down one percent or more.

VENTRACOR

Ventracor says it failed to reach the \$10 million target for its share plan and placement and is "exploring strategic options".

Ventracor has 17,000 retail investors and fell to a low of three cents - a long way from its peak of \$3.81 on August 22, 2003 representing a market capitalization of \$620 million.

Ventracor's chief executive officer Peter Crosby told Biotech Daily from Europe that the company could be sold outright, there could be strategic investments and he did not rule out the possibility of a white knight investor.

Mr Crosby said he was in discussions with a number of companies and interest in Ventracor could come from competitors, other companies in the cardio-vascular space as well as private equity firms.

"We are not being wound up, we are not insolvent and not facing insolvency," he said.

Ventracor told the ASX that it was "open to opportunities including investment, acquisition, merger, or any other structure that maximizes shareholder value and allows the company to continue to drive the commercialization of the Ventrassist left ventricular assist device". The share plan and placement were intended to raise \$10 million to complete the bridge-to-transplant trial.

Ventracor spokeswoman Angela Edwards told Biotech Daily the company had \$11.4 million in cash at October 31, 2008 giving it sufficient funds to survive to March 2009.

Ms Edwards said no one had been dismissed from the company.

The company said that all funds subscribed in the plan would be returned, without interest.

Ventracor chairman John Ward said it was "particularly disappointing" that near completion of recruitment in the bridge-to-transplant trial it was unable to raise the funds.

"There are now almost 400 people who have been implanted with the Ventrassist LVAD and results to date have been very promising," Mr Ward said.

He said the filing of more than 2,500 pages of the first module of the application for pre-market approval with the US Food and Drug Administration moved the company "one step closer to full commercialization" of the Ventrassist device.

Ventracor was down 3.5 cents or 47.95 percent at 3.8 cents with 9.7 million shares traded.

ARANA

Arana has begun a multi-centre phase II dose ranging study of its compound ART621 for rheumatoid arthritis.

Arana said recruitment of 200 patients for the trial was expected to take 12 months with the formal results of the study available in mid-2010.

The company said the first investigator meeting for the project was held in Sydney yesterday with personnel from 12 sites in Australia, New Zealand and the US.

Separate meetings will be held in early 2009 for the other 31 sites in Argentina, the Czech Republic, Poland, India and Malaysia.

Arana said study ART621/221 was a randomized, double-blind, placebo-controlled study designed to establish the efficacy of ART621 in rheumatoid arthritis and will compare three doses of ART621 with a placebo in patients also taking methotrexate (MTX).

Arana's acting chief executive officer Dr Steffen Nock said the company now had "two ongoing studies in rheumatoid arthritis [with] the results of our phase II psoriasis study expected in early 2009".

"This clinical data will be key in furthering our partnering discussions," Dr Nock said.

"The clinical progress of ART621 confirms the utility of Arana's antibody engineering to design next generation products for these important and very large markets," he said.

Arana climbed half a cent or 0.61 percent to 82 cents.

CSL

CSL has a \$270 million budget for research and development employing 750 scientists across more than 40 projects.

CSL's director of research and development and chief scientific officer Dr Andrew Cuthbertson told an investor and media telephone conference that the company had 35 medical graduates and about 150 PhD scientists on its payroll investigating a raft of projects from basic research to phase III trials.

While blood products were most significant, the company was also evaluating further variations of Gardasil, adding five more human papillomavirus serotypes to the existing four, along with research into influenza vaccines, H5N1 pandemic vaccines and drugs for Alzheimer's disease, inflammatory disease, rheumatoid arthritis, asthma, spinal cord injury, cancer and acute myeloid leukemia. He said there were three major clinical trials of influenza vaccines for adults, people at risk and children.

Dr Cuthbertson said immune responses to the CSL pandemic vaccine in children had been shown to last for up to six months.

He said work on infusions of reconstituted high-density lipoproteins or "good cholesterol" showed a reduction in thickness of atherosclerosis, but had possible liver toxicity issues. He said CSL was reformulating the reconstituted high density lipoprotein molecule to improve the therapeutic window.

"We have a coherent R&D strategy," Dr Cuthbertson said. "We are really forging our own path and not trying to be like a big pharmaceutical company. We are cost conscious, leveraging research with high quality academic groups."

He said that of the \$270 million budget, half was spent in Australia with the remainder in the Northern Hemisphere.

Dr Cuthbertson said \$90 million was spent on "true new product development" and CSL was "conscious of needing to build our pipeline".

He said CSL had a team looking for new projects and evaluating opportunities.

CSL director of public affairs, Dr Rachel David said the company was involved in "anything to do with proteins and immunology".

CSL fell \$1.50 or 4.56 percent to \$31.40 with 3.7 million shares traded.

CIRCADIAN TECHNOLOGIES

Circadian says it will be one of three principal sponsors of the 21st Lorne Cancer Conference in 2009.

Circadian which described itself as "a developer of novel antibody based drugs to treat cancer" said the annual event held in the seaside town of Lorne, on the Great Ocean Road in Victoria will take place on February 12-14, 2009 and would be attended by "some of the world's leading cancer researchers and drug development companies".

The 2009 conference will have more than 30 speakers with plenary lectures presented by cancer experts Dr Tyler Jacks of MIT, Dr Kenneth Kinzler of the Johns Hopkins Kimmel Cancer Center and Dr Alberto Montovani of the Humanitas Clinical Institute.

The principal sponsors are Circadian, the Cancer Council Australia and CSL.

Circadian managing director Robert Klupacs said the sponsorship was "in line with the recent transformation of our business to focus on our leading intellectual property position in the field of tumor angiogenesis and our expertise in antibody-based drug development." Circadian said it would fund an award for research excellence in angiogenesis or the growth of new blood vessels, a process involved in cancer.

For more information about the conference go to www.lornecancer.org.

Circadian climbed five cents or 8.33 percent to 65 cents.

HEALTHLINX

Healthlinx says it has exchanged "letters of intent" to have its Ovplex ovarian cancer test registered and sold in the United Kingdom for the next 10 years.

Healthlinx said the distributor would be Intus Healthcare, a UK-based medical device and diagnostic distribution company.

Intus is a distributor for corporations including Sunrise Medical, Cardinal Health, Fisher & Paykel, Health Solutions Inc, Weinmann Medical Technology.

Intus' managing director Martin Heller said his company had researched the diagnostic and "we realized that Healthlinx had made a major step in helping women worldwide with a disease that has seen little change in its survival rates in over 20 years".

"Intus is committed to bringing Ovplex to the UK market in 2009," Mr Heller said.

Healthlinx said Ovplex had a diagnostic efficiency for early stage ovarian cancer of 92.9 percent compared to the existing reference test CA125 at 60 percent.

This week Healthlinx said its second generation test had 98 percent efficiency (see Biotech Daily December 8, 2008). Managing director Nick Gatsios said on December 8 it would take three years from major market sales for the company to be in profit.

The company said Intus would be granted exclusive rights to Ovplex for 10 years with an option for a further 10 years.

Ovarian cancer is the United Kingdom fourth deadliest women's cancer. More than 6,800 women are diagnosed with the disease each year and more than 4,500 women die from the disease. About 1.3 million units of the CA125 test are sold each year in the UK.

Mr Gatsios said Europe was a priority Ovplex market. He said Intus would have a first right to additional European markets based on performance in the UK.

Healthlinx was up one cent or 20 percent to six cents.

VIRAX HOLDINGS

Virax has vaccinated the first of 140 participants in its South African phase I/IIa clinical trial of its HIV immunotherapeutic vaccine, VIR201.

Virax chief executive officer Dr Larry Ward said the beginning of the trial "in a country at the front-line of the battle with HIV/AIDS is a major milestone for the development of VIR201 and its underpinning technology, Co-X-Gene".

"This trial will build significantly on the previous Australian trials of VIR201 where it showed great promise in its ability to suppress the levels of HIV in individuals receiving the vaccine," Dr Ward said. "The vaccination of our first participant reflects an enormous amount of work and perseverance by our ... employees, the donor syndicate and the various organizations including the clinical sites involved in the trial," Dr Ward said.

The trial is funded by a coalition of mining companies through a donor syndicate.

The trial is designed to assess the safety, tolerability and immunogenicity of VIR201 in two HIV-infected groups: participants who have never received antiretroviral treatment; and participants on a stable antiretroviral treatment regime.

Previous Australian trials studied participants on a stable antiretroviral treatment regime.

To boost the immune response, in comparison to that observed in prior clinical testing, an increased dose of a more highly purified VIR201 vaccine is being used.

A comprehensive immune monitoring program will be undertaken to measure and compare the antibody and T-cell immune responses in both participant groups.

Dr Ward said the Australian trial did not measure an immune response that correlated with VIR201's ability to suppress viral load. He said the demonstration of a significant immune response would enhance the prospects of development and commercialization of VIR201.

Virax was untraded at 2.8 cents.

LIVING CELL TECHNOLOGIES

Living Cell says its neurotrophin cell, encapsulated brain choroid plexus cells, may be beneficial in Parkinson's disease.

Living Cell said that rats with induced Parkinson's disease showed improved limb function and significantly more surviving brain cells after they received implants of its neurotrophin cell.

The company said it was evaluating the neurotrophin cell for other brain diseases.

The data supported extending the clinical indication of the neurotrophin cell to include Parkinson's disease and Living Cell said it had filed a patent to extend its intellectual property to include the use of neurotrophin cell in this indication.

The company said brain choroid plexus cells produced cerebrospinal fluid which contained brain growth factors and proteins (neurotrophins) which supported the survival and growth of brain cells.

In the study, porcine choroid plexus cells were implanted to supply neurotrophins to repair diseased brain tissue.

The choroid plexus cells were encapsulated in a gel derived from seaweed to protect them from immune rejection and to permit implantation without using toxic anti-rejection drugs.

Neurotrophin cell capsules were surgically placed into the area of the brain affected by Parkinson's disease.

Compared with controls, treatment with neurotrophin cell was followed by normal use of the affected limb and recovery from the abnormal turning behavior characteristic of the disorder in rats.

The affected part of the brain of the treated animals showed more dopamine containing cells, the typical cells lost in Parkinson's disease.

Parkinson's disease affects 107 people per 100,000 worldwide and occurs more frequently with increasing age.

Living Cell said Parkinson's disease was caused by degeneration of the cells in the brain that regulate dopamine.

As the dopaminergic brain cells die, the dopamine supply decreases and becomes irregular and the activity of nerves that regulate muscle tremor malfunction.

As the degeneration continues, tremors become increasingly frequent and pronounced.

The company said that cell degeneration had many causes but the principal cause was decreased production of local brain hormones.

Current treatment with dopamine replacement is usually effective initially but wanes over time.

Living Cell has previously published data on the effects of choroid plexus transplants in the treatment of brain diseases and additional publications include studies demonstrating that neurotrophin cell implants also benefit rats with Huntington's disease and stroke.

Living Cell said neurotrophin cell was its "pipeline product in development" supported by a grant from the New Zealand Government's Foundation for Research Science & Technology.

Living Cell said the Foundation also funded the lead product Diabecell for the treatment of insulin dependent type 1 diabetes.

The encapsulated porcine Islets of Langerhans in Diabecell are in phase I/IIa clinical trials in Russia and New Zealand.

Living Cell was up 2.5 cents or 23.81 percent to 13 cents.

VICTORIA PREMIER'S AWARD

Nominations have opened for the 2009 Victorian Premier's Award for Health and Medical Research.

In a media release, Victoria's Premier John Brumby said the awards were a pathway to developing the depth of scientific talent.

"The Victorian Government is taking action to support innovation and has committed over \$2.1 billion to its Innovation Agenda, the largest such commitment of any State Government," Mr Brumby said.

The Award program provides \$40,000 in prize money with \$16,000 for the winner and \$8000 each for three commended applicants.

The Jack and Robert Smorgon Families will also present a \$30,000 Award to a research institute associated with the work of the Premier's Award winner.

"This prestigious award is an opportunity for our leading early career researchers to earn well-deserved recognition for their work," Mr Brumby said.

"Past winners have worked in many different health and medical fields, all contributing to Victoria's international reputation for pioneering research which is improving people's lives and strengthening our 21st Century economy," Mr Brumby said.

The Premier's Award for Health and Medical Research is an initiative of the Victorian Government and the Australian Society for Medical Research.

Nominations are open until 17 February 2009.

For further information and to apply online visit www.business.vic.gov.au/premiersawards or call the Australian Academy of Technological Sciences and Engineering, which is managing award applications, on +613 9340 1202.