Biotech Daily

Friday December 12, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: VIRALYTICS UP 43%, TYRIAN DOWN 23%**

*** GENETIC TECH DR MERVYN JACOBSON CHARGED; RESIGNS**

*** VIRALYTICS CAVATAK KILLS HUMAN BRAIN TUMORS IN MICE**

*** OREGON BACKS CYTOPIA FOR BONE CANCER, RHEUMATOID ARTHRITIS**

*** PSIVIDA BEGINS MEDIDUR TRIAL FOR MACULAR DEGENERATION**

*** CELLSCREEN TO RAISE $10m TO TAKE HPV TEST TO MARKET**

*** NANOSONICS PROBE DISINFECTOR PREPARING FOR 2009 LAUNCH**

*** MEL BRIDGES JOINS GENERA BOARD; DR MATT HARRIS RESIGNS**

*** SIRTEX v DR BRUCE GRAY: ROUND 11, DECEMBER 19**

*** NEURODISCOVERY REQUESTS NSL043 DEVELOPMENT TRADING HALT**

*** CORRECTION: VICTORIA PREMIER'S AWARD WEBSITE**

MARKET REPORT

The Australian stock market fell 2.3 percent on Friday December 12, 2008 with the All Ordinaries down 81.7 points to 3,452.5 points. Nine of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and 13 were untraded.

Viralytics was best up 1.3 cents or 43.33 percent to 4.3 cents with 495,000 shares traded, followed by Bionomics up 11.11 percent to 20 cents and Prana up 10 percent to 33 cents.

Polartechnics climbed 8.33 percent; Neuren was up 7.14 percent; Pharmaxis was up 4.76 percent; Biota climbed 3.28 percent; with Arana and Phosphagenics up more than one percent.

Tyrian led the falls, down 0.9 cents or 23.08 percent to three cents with 101,781 shares traded, followed by Antisense down 20 percent to 3.2 cents and Labtech down 15.38 percent to 16.5 cents.

Acrux and Ventracor lost more than 13 percent; Phylogica fell 11.11 percent; Chemgenex shed nine percent; CSL was down 7.01 percent; Alchemia and Cochlear fell more than four percent; Living Cell lost 3.85 percent; with Novogen down 1.49 percent.

GENETIC TECHNOLOGIES

After the market closed Genetic Technologies said that founder, director and major shareholder Dr Mervyn Jacobson has resigned "pending the determination of charges laid against him under section 1041A of the *Corporations Act* 2001 by the Commonwealth Director of Public Prosecutions".

The company said it would appoint additional directors to join its board.

Dr Jacobson spilled the board at the company's annual general meeting in November and with co-founder director Fred Bart appointed Huw Jones and Sid Hack as directors (see Biotech Daily November 19, 2008).

Genetic Technologies earlier requested a trading halt pending an announcement on "the composition of the board".

Genetic Technologies last traded at 3.8 cents.

VIRALYTICS

Viralytics says it has demonstrated the first step to proof-of-concept with the destruction of human brain tumors in mice by its lead product, Cavatak.

Viralytics said the research was conducted in collaboration with the University of Newcastle and University of Toronto neurosurgeon Prof Abhijit Guha investigating the oncolytic activity of Cavatak in mouse models of human brain cancer.

Viralytics said that earlier this year, the University of Newcastle's Dr Gough Au delivered a poster presentation covering the positive oncolytic activity of Cavatak in laboratory cell cultures of human brain cancer at the Hunter Medical Research Institute Conference on Translational Cancer Research, September 10-12, 2008 in Newcastle (available at www.viralytics.com under Scientific Publications).

The company said that more recently, researchers at the University of Newcastle have demonstrated the destruction of human brain tumors by Cavatak.

In these studies, glioblastoma multiforme tumors were grown on the backs of immune-compromised mice.

A single dose of Cavatak was injected directly into the tumor. About three weeks after the Cavatak injection, little to no tumor deposits could be detected in the mice. The company said that tumors injected with a normal saline solution were shown to be expanding rapidly. Prof Guha said the data generated from the pre-clinical studies on the oncolytic activity of Cavatak against laboratory cultures of glioblastoma multiforme and initial mouse glioblastoma multiforme xenograft studies was "very exciting and warrants progression to higher levels of evaluation, prior to possible clinical evaluation".

Viralytics said that numerous biopsies of different types of human brain cancer supplied by Prof Guha had undergone biochemical analysis at the University of Newcastle.

The company said the testing showed that "highest levels of the Cavatak cell surface binding molecule (ICAM-1) were consistently present on cells from glioblastoma multiforme, the most aggressive form of glioblastoma.

The presence of ICAM-1 is required to permit Cavatak infection and destruction of the tumor cells, Viralytics said.

Viralytics chief scientific officer Prof Darren Shafren said the data accumulated from the research collaboration supported findings in other cancer types previously generated in pre-clinical studies and from current phase I clinical trials.

"The studies demonstrate the anti-cancer activity of Cavatak when directly injected into solid tumors expressing high levels of ICAM-1 and/or DAF molecules," Prof Shafren said.

Viralytics said the next phase in the pre-clinical studies was to administer Cavatak into glioblastoma multiforme tumors grown within the brains of immune-compromised mice.

Viralytics climbed 1.3 cents or 43.33 percent to 4.3 cents.

CYTOPIA

Oregon Health & Science University says its researchers have found that Cytopia's CYT387 blocks an enzyme that causes some bone marrow cancers.

The University said researchers at its Knight Cancer Institute tested CYT387 in mice as well as in human cells.

In both cases, it blocked the growth of myeloproliferative disorders, a form of bone marrow cancers.

The research was presented on December 9, 2008 at the annual American Society of Hematology conference in San Francisco.

Oregon researcher Dr Thomas Bumm said the drug was "very effective against a specific type of cancer cells, cancer cells which are driven by an enzyme mutation called JAK2-V617F".

"In the mouse model, the drug blocked JAK2-V617F, normalized blood counts and reduced enlarged spleens back to a normal size. It is a very promising compound," Dr Bumm said.

The University said in a media release posted on its website that the drug worked by binding to the V617F mutation in the JAK2 enzyme.

Without this drug, the mutated JAK2 enzyme leads to myeloproliferative disorders or MPDs.

The University said myeloproliferative disorders include polycythemia vera, essential thrombocythemia and primary myelofibrosis.

"Until now there have been no FDA-approved targeted treatments for these diseases," the University said.

The principal investigator Prof Michael Deininger who is also a professor of medicine at Oregon Health & Science University said that "based on the efficacy that we demonstrated in the mouse model, there is a good chance that CYT387 will enter clinical trials as early as 2009".

"Those in greatest need include patients with myelofibrosis, a relentless disease for which there is currently no effective therapy," Prof Deininger said.

"It is likely that JAK2 inhibitors will change the standard of care for these patients," Prof Deininger said.

The University said its researchers also discovered that CYT387 "effectively blocks overproduction of inflammatory cytokines".

Abnormal cells carrying the JAK2-V617F mutation produce a large amount of different inflammatory cytokines that help the cancer cells to grow and repress normal cells.

In mice, the drug normalized 19 different inflammatory cytokine levels in the blood.

The overproduction of cytokines can also be found in inflammatory conditions such as rheumatoid arthritis.

"This drug's effect on cytokines could benefit patients with inflammatory diseases, especially rheumatoid arthritis," the University said.

The next step will be to open clinical trials for people with myeloproliferative disorders once formal preclinical toxicology studies are completed. The announcement is at: http://www.ohsu.edu/xd/about/news_events/news/bonemarrow120908.cfm

Cytopia chief executive officer Andrew Macdonald previously said the company was "aggressively progressing this compound through formal preclinical studies with the aim of beginning clinical trials by the end of this year" (See Biotech Daily March 18, 2008).

Mr Macdonald said in March that the accumulated data for CYT387 clearly indicated that the compound had "an excellent potency and safety profile for the treatment of patients with myeloproliferative disorders".

Cytopia was untraded at 22 cents.

PSIVIDA

Psivida says a clinical trial has begun using Medidur delivery technology to treat a form of dry age-related macular degeneration.

Psivida said Medidur was “a tiny intravitreal insert designed to be administered by an eye care professional, using a 25-gauge inserter in a minimally invasive, outpatient procedure”.

The company said this application of Medidur technology had been licenced to Alimera Sciences and was in pivotal phase III clinical trials for the treatment of diabetic macular oedema, a potentially blinding disease that affects more than one million people in the US.

The phase III clinical trials were fully enrolled more than a year ago with preliminary efficacy and safety results expected in about one year.

If approved by the US Food and Drug Administration, Alimera will market the product under the name Iluvien, Psivida said.

Psivida said the new study was an investigator-sponsored pilot study designed to assess the safety and efficacy of Iluvien in patients with bilateral geographic atrophy, secondary to dry age-related macular degeneration and would compare two doses of Iluvien with a placebo.

Psivida public affairs director Brian Leedman told Biotech Daily the research was conducted at work was at the Kresge Eye Institute part of Michigan’s, Wayne State University School of Medicine in Detroit.

The Kresge Eye Institute’s Dr Raymond Iezzi said the impetus for the study “was the results of experiments conducted in two animal models of retinal degenerations”.

“In both of these models, a miniaturized version of Iluvien demonstrated protective effects on the spontaneous degeneration which occurs in these animals,” Dr Iezzi said.

“These results were considered compelling enough to warrant a human study, especially for a condition for which there is no approved treatment,” Dr Iezzi said.

Psivida’s managing director Dr Paul Ashton said the company was “pleased that another application of our Medidur technology has now entered clinical trials”.

Psivida was untraded at $1.40.

CELLSCREEN DIRECT

Cellscreen hopes to raise up to $10 million and list on the ASX to launch the Tam Pap test for human papillomavirus (HPV) and other molecular diagnostic tests.

The initial public offering is of 15,000,000 shares at 50 cents each “with a right to take oversubscriptions to ... 20,000,000 shares”.

The implied market capitalization on listing will be up to $31,313,750 million if the $10 million is raised. A minimum subscription has been set at $7.5 million.

Cellscreen describes its test as “a DNA, polymerase chain reaction (PCR) diagnostic test process the subject of a patent application that can genotype all strains of HPV, generally accepted in Australia, Europe and the US as ‘high oncogenic risk types’ to be acquired from Symbion on completion of the offer in exchange for shares in the company”.

The board of directors includes chair Alison Coutts (Martin Place Securities), former Federal Liberal Health Minister Dr Michael Wooldridge, managing director Dr Peter Hughes, Dr Adrian Cachia, Russell Tate and Warwick Doughty.

The offer opened on December 4, 2008 and closes on December 23, 2008.

Shares are expected to begin trading on January 6, 2009.

Cellscreen’s prospectus is at http://cellscreendirect.com/prospectus.html.

NANOSONICS

Nanosonics says it has achieved key commercial milestones relating to the launch of its Trophon Ultrasound Probe Disinfector.

The company's materials compatibility testing has received pivotal validation from leading ultrasound probe suppliers.

Nanosonics said that Philips Healthcare Ultrasound and Siemens Medical Solutions USA have "independently confirmed the in-house testing methodology and results of materials compatibility tests on a wide range of their ultrasound probes".

Both companies are supporting the marketing of Nanosonics Trophon EPR Ultrasound Probe Disinfector into the global market, the company said.

The company said the validations "further support the superior materials compatibility of the unique and proprietary Nanonebulant technology".

Nanosonics said clinical validation conducted in New South Wales confirmed the significant benefits of high level disinfection in reducing the risk of nosocomial infections between patients.

The company said it was "on-track for the international commercial release of the Trophon EPR Ultrasound Probe Disinfector in early February 2009".

Material orders were being received for the shipment of finished goods to the distribution partners in New Zealand, Australia and several European markets.

The manufacturing ramp-up is ahead of schedule, with production commencing mid-January prior to the February release, the company said.

Australian Therapeutic Goods Administration approval was on-track for finalization prior to commercial release of the product.

Nanosonics said the TGA was satisfied with the overseas certification and supporting reports and woudl not require a pre-release audit.

The final certification and evaluation is now pending sign off by the TGA and the company has marketing approval in the European Union, Canada and New Zealand, with a submission to the US Food and Drug Administration lodged prior to Christmas, 2008.

Nanosonics said it had accelerated its development program for additional products aimed at the global medical device market and was in discussion with corporations to bring forward the release of further products based on the Nanonebulant technology in the second half of 2009.

Nanosonics was up 1.5 cents or 8.33 percent to 19.5 cents.

GENERA BIOSYSTEMS

Genera says Mel Bridges will join the company as a non-executive director and Dr Matt Harris will be resign "to focus on his own business activities".

Genera chairman Fernando Careri said it was "a clear recognition of the quality of Genera's technology that we were successful in attracting a director of the experience and calibre of Mel Bridges to the Genera board".

"Mel has unparalleled experience in building successful diagnostics businesses here in Australia, a global network of valuable contacts and is undoubtedly a substantial figure in the world of biotech. I very much look forward to the contributions that he'll be making," Mr Careri said.

Mr Bridges is the chairman of Alchemia, Incitive and Impedimed. He is a former chairman of Peptech, now Arana and is a director of Benitec.

He was the founder and managing director of Pacific Diagnostics, sold to Baxter Corp in 1986 and was the founder and chief executive officer of Panbio.

Genera was up two cents or eight percent to 27 cents.

SIRTEX

The long running legal battle between Sirtex and cofounder and major shareholder Dr Bruce Gray will return to court on December 19, 2008.

Sirtex said today that Dr Gray had been successful in arguing that he should no longer be restrained from competing with the company under the terms of his employment when the company was established in 1997 and when it floated on the ASX in 2000.

Similarly Sirtex said Dr Gray had been successful in arguing that he should no longer be restrained from competing with the company under the terms of a subscription and shareholders agreement and a supplemental subscription and shareholders agreement.

Sirtex said Dr Gray had argued that both restraints were"unenforceable as unreasonable restraints of trade".

The company said that Dr Gray had argued that he ceased to hold shares in Sirtex for the purpose of the subscription and shareholders agreement on August 26 2008 "when his shares were acquired by a company owned and controlled by him".

Sirtex said a supplemental subscription and shareholders deed of July 17, 2000 caused the original agreement to cease to have effect at law on restraint.

"Having considered Dr Gray's amendment, Sirtex has informed Dr Gray and the court that it accepts Dr Gray's interpretation of the effect of the supplemental subscription and shareholders deed and no longer pursues its claim for injunctive relief," Sirtex said.

The company said the balance of the Dr Gray proceedings have been set down for further hearing on December 19, 2008.

Biotech Daily attempted to contact Sirtex to clarify what composed "the balance of the Dr Gray proceedings" but there had been no response at the time of publication.

Sirtex fell one cent or 0.58 percent to $1.72.

NEURODISCOVERY

Neurodiscovery has requested a trading halt pending an announcement "in relation to its NSL 043 development program".

Trading will resume on December 16, 2008 or on an earlier announcement.

Neurodiscovery last traded at five cents.

CORRECTION: VICTORIA PREMIER'S AWARD

Yesterday's edition reported that nominations had opened for the 2009 Victorian Premier's Award for Health and Medical Research.

A website address www.business.vic.gov.au/premiersawards was provided which should be operational by the time this edition is published. An alternative address is http://www.business.vic.gov.au/BUSVIC/STANDARD//PC_60159.html.

For further information call the Australian Academy of Technological Sciences and Engineering, which is managing the award applications, on +613 9340 1202.