



Biotech Daily

Monday May 5, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: LIVING CELL UP 18.5%, PHARMAXIS DOWN 10.5%**
- * **HEARING CRC: 'HEARING AIDS MAY DELAY DEMENTIA'**
- * **IMMURON CLEARS PALADIN \$1.5m DEBT**
- * **NOVOGEN FORMS CHILDREN'S ONCOLOGY DRUG ALLIANCE**
- * **CLINICAL GENOMICS BLOOD TEST FOR BOWEL CANCER**
- * **BELLBERRY \$400k FOR 5 JAMES COOK UNIVERSITY RESEARCHERS**
- * **VIRAX LICENCE OPTION FOR P27 CANCER BIOMARKER TEST**
- * **WEBINVEST TAKES 7% OF IMUGENE**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Monday May 5, 2014 with the S&P ASX 200 up 4.1 points to 5,462.2 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and six were untraded.

Living Cell was the best, up 1.2 cents or 18.5 percent to 7.7 cents with 274,398 shares traded.

Clinuvel climbed 9.6 percent; Alchemia was up 6.9 percent; Analytica, Antisense, IDT and Tissue Therapies were up more than three percent; Impedimed, Mesoblast and Nanosonics rose more than two percent; Acrux, Cochlear and Universal Biosensors were up more than one percent; with CSL, GI Dynamics, Psivida and Sirtex up by less than one percent.

Pharmaxis led the falls, down 0.8 cents or 10.5 percent to 6.8 cents with 1.1 million shares traded.

Anteo lost 7.7 percent; Biotron, Ellex and Viralytics fell more than six percent; Oncosil and Patrys were down more than five percent; Bionomics fell 4.5 percent; Benitec, Cellmid, Neuren and Starpharma shed more than three percent; with Prima down 2.7 percent.

[HEARING COOPERATIVE RESEARCH CENTRE \(CRC\)](#)

The Melbourne-based Hearing CRC says that hearing technologies could play an important role in delaying dementia.

The Hearing CRC said that Macquarie University's Prof Stephen Crain will tell a World Congress of Audiology's Roundtable on Central Auditory Plasticity in Melbourne tomorrow May 6, 2014 that the degree of hearing loss was highly correlated with the risk of dementia and "intervention with a hearing device to restore hearing in adulthood could assist in delaying the onset of dementia".

Prof Crain said that central auditory plasticity was the adaptability of the brain's cerebral cortex to process sound more effectively in response to new stimuli.

"We now know the brain has a remarkable ability to re-grow and adapt itself to process new kinds of information and relearn tasks, especially in early childhood, but across the lifespan," Prof Crain said.

"Some of the best evidence for this comes from a brain imaging technique known as magneto-encephalography, or MEG, which measures tiny magnetic fields that are activated throughout our brains whenever we process information," Prof Crain said.

"Through MEG, researchers have been able to gain a better understanding of which areas of our brains are used to process certain kinds of information, including language," Prof Crain said.

"An example of one of the biggest discoveries made using brain imaging was learning that blind subjects process auditory information in both the brain's visual and auditory cortex," Prof Crain said.

The Hearing CRC said that the peak of brain's central auditory plasticity occurred in children between the ages of two and four years.

The Hearing CRC said that before this time infants with hearing loss benefitted most from a hearing device, so that the regions of the brain that processes sound information and language could develop most optimally.

"Studies clearly show that children with hearing loss fitted with hearing devices at a young age achieve better language skills as compared to unfitted children with hearing loss and even children who are fitted later with these devices," Prof Crain said.

"Although the brain has its greatest plasticity in very young children, it continues to have remarkable adaptive abilities at all ages," Prof Crain said.

"Our research at the [Australian Research] Centre of Excellence in Cognition and its Disorders in conjunction with the Hearing Cooperative Research Centre is using MEG to better understand how both child and adult brains process and adapt to the sound information received from cochlear implants and hearing aids," Prof Crain said.

The Hearing CRC said that preliminary research supported the notion that adults with hearing aids developed new neural pathways in the brain to more fully use the information created by the devices.

The Hearing CRC said that to some extent this conclusion was supported by anecdotal evidence that many adults who were initially unhappy with their hearing devices suddenly reported dramatic improvement a month or so later.

"We don't know yet exactly what is happening in the brains of these adults, but their observations suggest that perceptual processing changes are taking place in the brain as it adjusts to the information provided by hearing devices," Prof Crain said.

"It's early days but as the degree of hearing loss is highly correlated with the risk of dementia it seems highly likely that intervention with a hearing device to restore hearing in adulthood could assist in delaying the onset of dementia," Prof Crain said.

IMMURON

Immuron says that its \$C1.5 million (\$A1.48 million) debt to Paladin Labs has been repaid. Immuron said that in 2011 Paladin Labs provided debt financing when the two companies entered into a licence agreement for the distribution of Travelan in Canada and other countries.

Immuron said the two companies prepared an application for regulatory approval and in November 2013, Health Canada granted that approval and it was expected that Travelan would be launched in Canada.

The company said that the debt facility enabled it to continue to fund its operations without encumbering any of its intellectual property and other core assets.

Immuron said that following the raising of \$9.66 million it no longer required the debt financing from Paladin (BD: Feb 26, 2014).

Immuron chief executive officer Amos Meltzer said "we have now removed Immuron's significant ongoing interest payment obligations as well as strengthened the balance sheet".

Immuron was unchanged at 0.55 cents.

NOVOGEN

Novogen says it has joined researchers and advocates in Australia and the US to form the Children's Oncology Drug Alliance to develop treatments for children with cancer.

Novogen said that Alliance included the University of New South Wales, the Sydney-based Kids' Cancer Project childhood cancer research charity and the Nationwide Children's Hospital in Columbus, Ohio.

The company said that the Alliance's mission was to help accelerate development of innovative therapeutic approaches to the treatment of childhood cancers, but neuroblastoma in particular.

University of New South Wales head of the oncology research Prof Peter Gunning said that childhood cancers had been neglected despite the progress made with treatments for adult cancers.

"The Alliance brings together the science, expertise and funding to accelerate the development of a medicine that has the potential to change the way we treat solid cancers in children," Prof Gunning said.

Novogen said that there was no approved treatment for neuroblastoma, a cancer that affected up to 100 children in Australia and about 650 in the US each year.

The company said that childhood cancers were treated with chemotherapies developed for adults, with little consideration to the special needs of children.

Novogen said it was providing access to its technologies to facilitate the development of the first chemotherapy for childhood solid cancers such as neuroblastoma.

Novogen chief executive officer Dr Graham Kelly said that "the Holy Grail of childhood cancer therapy is a medicine that is effective against a tumor such as neuroblastoma, but doesn't leave the sort of damage that the child then has to deal with for the rest of his or her life".

"We believe that the two drug technologies we have developed have the potency, selectivity and safety profile to meet the special needs of children," Dr Kelly said.

Novogen said it was finalizing pre-clinical research on its drug candidates with the goal of starting clinical studies in Australian and the US in 2015 and intended to progress the paediatric trials in neuroblastoma in parallel with trials of anti-tropomyosins and super-benzopyrans for adult cancers.

Novogen was up half a cent or 2.9 percent to 17.5 cents.

CLINICAL GENOMICS

Clinical Genomics says its bowel cancer blood test can detect 65 percent of bowel cancer cases and 73 percent for cancers that are stage II or higher.

Clinical Genomics chief executive officer Dr Larry LaPointe told Biotech Daily that a prospective, blinded clinical trial in 2,109 participants showed that the cancer-specific test had an estimated sensitivity of 65 to 70 percent for cancers at any stage and an estimated specificity of 92 to 94 percent.

Dr LaPointe said the study was conducted at Adelaide's Flinders University Centre for Innovation in Cancer and the Amsterdam, Netherlands-based Academic Medical Centre. Clinical Genomics said that data on the blood test was based on two genes that leak into the blood stream and was presented at the Digestive Diseases Week conference in Chicago by Flinders Centre for Innovation in Cancer's Prof Graeme Young.

Prof Young said that the test could be a candidate for population screening and its sensitivity for cancer justified prospective evaluation in a large screening population.

"If this test becomes available in the future I think the message would need to be that the faecal test is the best place to start for people who are due for screening," Prof Young said. "Then the plasma test would be for those people who can't or won't screen with a faecal test."

Clinical Genomics said it co-developed the test with the Commonwealth Scientific and Industrial Research Organisation and it had been clinically validated in collaboration with the Flinders Centre for Innovation in Cancer.

Dr LaPointe said the test was covered by a range of pending patents and could be available on a user pays basis as soon as September 2014.

Clinical Genomics is a private company.

BELLBERRY

Private ethics review company Bellberry says it has provided \$400,000 to five researchers at the Australian Institute of Tropical Health and Medicine at James Cook University.

The Townsville, Queensland-based James Cook University Faculty of Medicine's pro-vice-chancellor Prof Ian Wronski said the five researchers were "working on projects that already show a great deal of potential to prevent or treat debilitating or deadly conditions".

Bellberry chief executive officer Kylie Sproston said her organization aimed to promote and improve the welfare of research participants, while supporting Australian research.

"All of these [Australian Institute of Tropical Health and Medicine] projects are at an important stage of their development, where an injection of funds can make a significant difference," Ms Sproston said.

"The projects range from research into treatments of inflammatory diseases such as asthma and childhood type 1 diabetes, through to dangerous common parasites and aortic aneurysms," Ms Sproston said.

"All have potential benefit not only in the Australasian region but for health and medicine outcomes around the world," Ms Sproston said.

Bellberry said that the five recipients were Prof Nick Smith who was working on a vaccine against the common parasite *Toxoplasma gondii*; Prof Norelle Daly who was exploring the potential of peptides, or small proteins, found in some plant species, for the treatment of cancer; Prof Alex Loukas who would use the funds to further investigate the potential of proteins from parasitic hookworms to treat inflammatory diseases such as asthma; Prof Jon Golledge who was aiming to develop a new protein-based treatment for patients with aortic aneurysms; and Prof Alan Baxter who was investigating type 1 diabetes.

VIRAX HOLDINGS

Virax says it has a licence option with the Moffitt Cancer Center for a p27 protein test allowing selection of cancer patients likely to respond to its GGTI-2418.

In March, Virax began the process to acquire Pathway Oncology, which held a licence to the GGTI-2418 compound which blocks the cancer growth enzyme geranyl-geranyl transferase I (BD: Mar 17, 2014).

Virax said at that time that GGTI-2418 was developed at the New Haven, Connecticut-based Yale University and the University of South Florida and invented by Florida's Moffitt Cancer Center director of drug discovery Prof Said Sebti and Yale's former provost and now Oxford University vice-chancellor Prof Andrew Hamilton.

Today, Virax said that in normal cells, the cyclin-dependent kinase inhibitor p27 played a key role in regulating cell division, but in some cancer types, including breast cancer, p27 was expressed at very low levels and this contributed to the uncontrolled cell division, a major hallmark of cancer.

The company said that the lower the p27 levels, the worse the patient outcomes.

Virax said that GGTI-2418 increased the levels of p27 in the nucleus and, by doing so, killed tumor cells and that patients whose tumors expressed very low levels of p27 and where GGTI-2418 increased these levels were more likely to respond to GGTI-2418.

The company said that GGTI-2418 was thought to inhibit the geranyl-geranylation of the protein Rho, thereby inactivating the protein.

Virax said that in cancer cells, overactive Rho was thought to lower the levels of the p27 which normally acted as a brake on the cell cycle and GGTI-2418 could therefore inactivate Rho leading to higher levels of nuclear p27 stopping aberrant growth.

Virax executive chairman Dr Wayne Millen said the company planned to add the diagnostic tool to its portfolio shortly after completion of the Pathway Oncology acquisition which goes to shareholders for approval on May 9, 2014.

"The p27 technology will allow us precision in determining those patients who are more likely to respond to GGTI -2418 therapy," Dr Millen said.

Virax said the technology presented a method of using baseline nuclear p27 expression level in the breast tumors as a biomarker for response to GGTI-2418 treatment and the data suggested that breast tumors with low baseline nuclear p27 expression where GGTI-2418 increases the levels were likely to benefit from the GGTI-2418 treatment.

Prof Sebti said that the demonstration that GGTI-2418 increased the levels of p27 and requires p27 to kill breast cancer cells, coupled with the poor prognosis of breast cancer patients with low levels of p27 "suggests that breast cancer patients whose tumors have low levels of p27 are more likely to respond to GGTI-2418 treatment".

Virax said that in 2013 more than 230,000 new breast cancer cases were diagnosed and almost 40,000 women died of the disease in the US and breast cancer was the most common cancer in women in Australia, suggesting that there was an unmet need for novel therapies to further reduce mortality.

Virax said that it would pay \$3,000 for the option and if exercised Virax would be granted an exclusive right to exploit the intellectual property portfolio in return for Virax paying for the future costs of maintaining the intellectual property portfolio and reimbursing Moffitt for some of its past costs; making minimum yearly payments to Moffitt and using reasonably commercial efforts to commercialize the technology; making lump sum payments to Moffitt upon achieving certain defined milestones; and paying to Moffitt commercial arm's length net sales revenue royalties in respect of any products that are commercialized.

Virax said that the exact terms of the licence agreement would be negotiated over the next three weeks.

Virax was unchanged at one cent with 7.1 million shares traded.

IMUGENE

The Trinity Beach, Queensland-based Webinvest said it increased its substantial holding in Imugene from 55,500,000 shares (5.86%) to 62,000,000 shares (7.06%).

Webinvest director Otto Buttula said the 6,500,000 shares were acquired on-market for \$93,472 or an average of 1.44 cents a share.

Imugene was unchanged at one cent with 1.7 million shares traded.