



Biotech Daily

Thursday June 19, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECHS DOWN: OPTISCAN UP 22.5%, PORTLAND DOWN 31%**
- * **BIONOMICS IN MULTIPLE \$50m DEALS WITH MERCK FOR MS**
- * **NSW, VIC GOVERNMENTS BACK STEM CELL RESEARCH WITH \$550k**
- * **VICTORIA-CALIFORNIA STEM CELL ALLIANCE**
- * **VICTORIA GOVERNMENT PROMOTES EPILEPSY, INFLUENZA RESEARCH**
- * **BONE LICENCES OSTEOPOROSIS PRODUCT TO KOREA'S HYUNDAI**
- * **COGSTATE EXPECTS RECORD REVENUE GROWTH**
- * **BIO-MELBOURNE: PATENT MANAGEMENT FOR BIOTECH COMPANIES**
- * **PROF COLIN CHAPMAN JOINS ANADIS BOARD AMID SEVERAL CHANGES**
- * **OPTISCAN APPOINTS DR JIM FOX, PAUL WRIGHT DIRECTORS**

MARKET REPORT

The Australian stock market fell 1.2 percent on Thursday June 19, 2008 with the All Ordinaries down 66.0 points to 5,484.3 points. Nine of the Biotech Daily Top 40 stocks were up, 19 fell, nine were unchanged and three were untraded.

Optiscan was best, up 4.5 cents or 22.5 percent to 24.5 cents on modest volumes, followed by Stem Cell up 6.5 cents or 18.57 percent to 41.5 cents and Benitec up one cent or 12.2 percent to 9.2 cents with 1.9 million shares traded.

Peplin climbed 6.76 percent; Bionomics was up 5.56 percent; Cellestis and Polartechnics were up four percent or more; with Phylogica up 2.22 percent.

Portland led the falls, down 1.1 cents or 31.43 percent to 2.4 cents on modest volumes, followed by Sunshine Heart down 16.67 percent to five cents, Cytopia down 13.04 percent to 20 cents and Novogen down 12.71 percent to \$1.27.

Agenix lost 8.77 percent; Alchemia fell 6.58 percent; Clinuvel, Prana and Sirtex fell more than four percent; Antisense, Avexa, Chemgenex, Cochlear, Mesoblast and Resmed were down more than three percent; Biota and CSL shed more than two percent; with Circadian, Genetic Technologies, Progen and Ventracor down more than one percent.

BIONOMICS

Merck Serono will pay Bionomics multiples of \$50 million to develop treatments for multiple sclerosis and other autoimmune conditions based on compounds from Bionomics Kv1.3 program.

Bionomics said Merck Serono was a division of Germany's Merck KGaA.

The compounds discovered by Bionomics, around which the collaboration will focus, target the potassium ion channel Kv1.3.

Bionomics said Kv1.3 was a key modulator of the immune system and it was a target found on human immune cells which were associated with nerve cell damage in patients with multiple sclerosis.

Inhibitors of Kv1.3 have been shown to inhibit the proliferation of these immune cells, suggesting that they have application in the treatment of multiple sclerosis and potentially other autoimmune conditions, including arthritis.

Bionomics said it would receive an upfront payment of \$US2 million and committed research funding.

Merck Serono will fund all development activities, including clinical development.

Merck Serono intends to select compounds from Bionomics' pool of compounds and for each compound selected by Merck Serono, Bionomics may receive milestone payments of up to \$US47 million (\$A49.7 million) per compound, based on successful development and commercialization.

In addition, Bionomics will be eligible to receive undisclosed royalties on the net sales of licensed products.

Merck Serono's executive vice-president of research Dr Bernhard Kirschbaum said the partnership with Bionomics "reflects our long-term commitment to patients with MS as Kv1.3 inhibition represents an innovative approach for the discovery of oral compounds in the field of MS".

He said the research and development collaboration brought together "Bionomics' expertise in Kv1.3 biology and Merck Serono's expertise in [multiple sclerosis] pharmacology in a combination that could speed up progress in the identification of novel drug candidates for the treatment of [multiple sclerosis]".

Bionomics chief executive officer Dr Deborah Rathjen said Merck Serono was "the ideal partner for Bionomics in this Kv1.3 program".

"The agreement with Merck Serono is an important milestone for our company," Dr Rathjen said.

"It validates Bionomics' discovery approach, which has brought the program to this stage," Dr Rathjen said.

"We look forward to working with Merck Serono in the next stage to bring innovative treatment options for patients with [multiple sclerosis] to the clinic".

Bionomics said multiple sclerosis was a chronic, inflammatory condition of the nervous system and is the most common, non-traumatic, neurological disease in young adults.

The World Health Organization estimates that up to 2.5 million people have multiple sclerosis. The relapsing forms of multiple sclerosis are the most common.

Merck Serono is a leader in multiple sclerosis with Rebif (interferon beta-1a), a disease-modifying drug used to treat relapsing forms of multiple sclerosis, which is registered in more than 80 countries worldwide.

Merck Serono has a second therapy, Novantrone (mitoxantrone for injection concentrate) for worsening forms of multiple sclerosis. Other options are under development, including oral cladribine, currently in phase III and potentially the first oral therapy for multiple sclerosis, as well as several products in early stage development.

Bionomics climbed two cents or 5.56 percent to 38 cents.

NEW SOUTH WALES, VICTORIA GOVERNMENTS

The New South Wales and Victorian Government have provided \$550,000 to Sydney IVF and the Australian Stem Cell Centre for collaboration on stem cells from skin cells.

Victorian Innovation Minister Gavin Jennings and NSW Minister for Science and Medical Research Verity Firth announced the grants at BIO 2008 in San Diego.

Sydney IVF and the Melbourne's Australian Stem Cell Centre will compare induced pluripotent stem cells (cells generated from skin cells) with stem cells derived from embryos or from a somatic cell nuclear transfer process using clinically unusable eggs.

The researchers hope to develop a routine, repeatable method of making patient-specific stem cells within the nationally approved legislative guidelines.

A media release from the two Governments said somatic cell nuclear transfer (SCNT) used a patient's own cells to create a source of individually tailored embryonic stem cells. For patients with a specific disease, these stem cells will have unique characteristics that may be used to better understand and treat the disease process.

The Governments said the work was possible "due to the new funding and recent changes to legislation in both Victoria and NSW, opening up opportunities for SCNT research to occur in Australia".

"This important initiative will put Australian scientists yet again at the forefront of stem cell research," said Mr Jennings.

"The promise of pluripotent stem cells is vast because they have the potential to develop into specialized cells that could be used as replacement cells and tissues to treat many diseases and conditions, help us to understand what causes birth defects and cancer and change the way we develop and test drugs," Mr Jennings said.

Scientists from Japan and America made the discovery that stem cell-like cells could be made from human skin cells in late 2007.

Sydney IVF will undertake the SCNT work in this program.

The Australian Stem Cell Centre will perform the characterization and comparison of the stem cell-like cells.

"The research talent and significant resources of these two collaborative partners gives this project the potential to provide world-first advancements in these new biological frontiers," Ms Firth said.

"Both the NSW and Victorian Governments are proud to be supporting this ground-breaking work, which we believe will offer new hope to people living with debilitating diseases such as rheumatoid arthritis, Alzheimer's disease and Parkinson's disease," Ms Firth said.

The media release said recent US research had turned embryonic stem cells into insulin producing cells in mice, representing a possible cure for type 1 diabetes and there was already proof-of-concept that stem cells could restore function to damaged tissues in models of Parkinson's disease and immuno-deficiency.

"Victoria and NSW have now come together to extend our leadership into new stem cell technologies which have the potential to transform how we treat major and growing diseases like diabetes, heart disease, cancer and Parkinson's," the Ministers said.

Ms Firth said that in July 2008 the NSW Government would commence a program to provide scholarships for doctorate of philosophy research into induced pluripotent stem cells, to ensure that Australia continues to develop researchers "at the cutting edge of stem cell technologies".

The scholarship program will be named in honor of Dr Paul Brock in recognition of his efforts in promoting innovative research into serious diseases, in particular motor neurone disease.

VICTORIA-CALIFORNIA

Victoria's Premier John Brumby and Innovation Minister Gavin Jennings signed the Victoria-California Stem Cell Alliance to establish a pan-Pacific "stem cell airbridge". Describing the agreement as "historic" a Victorian Government media release said the collaboration between Victoria and the California Institute of Regenerative Medicine would empower California scientists to help turn Victorian discoveries into worldwide treatments. Mr Brumby and Mr Jennings signed the agreement with the Institute's president Prof Alan Trounson and chairman Robert Klein.

"Victoria and California are world leaders in biotechnology and stem cell research," Mr Brumby said.

"The stem cell alliance builds on existing links between California and Victoria in information and communications technology and climate change," Mr Brumby said.

"We are two of the world's leading jurisdictions in tackling the leading global issues and we share the common goal of helping our best and brightest to tackle these issues."

Mr Jennings said the alliance would help establish strategic, collaborative projects on stem cell research with a particular focus on accelerating treatments of disease.

"We have led this field from the very start with Alan Trounson's pioneering work in IVF and, in recent times, the discovery of breast stem cells at the Walter and Eliza Hall Institute," Mr Jennings said. "But no jurisdiction can do it alone, so it makes sense to connect with powerful partners such as California."

Prof Trounson said that accelerating stem cell research was a primary goal. "In some instances, we can do this more effectively through collaborations that involve the best scientific endeavors, regardless of geography," Prof Trounson said.

The California Institute of Regenerative Medicine was established in 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act and has approved 168 research and facility grants worth more than \$US530 million.

The media release said a "stem cell air bridge" between California and Australia would advance the network of relationships and shorten the time that it takes to bring discoveries into the clinic and to patients.

Under the Institute and the State of Victoria three-year agreement the two bodies will jointly seek grant applications, evaluate them and make finding recommendations.

The initial avenue for collaboration will be the CIRM disease team grants to provide an opportunity for researchers in California and Victoria to collaborate.

VICTORIA GOVERNMENT

Epilepsy

Victoria's Innovation Minister Gavin Jennings says Melbourne doctors have developed a genetic test to predict the response of epileptics to drug treatments.

Mr Jennings said the blood-based test had been developed by doctors from the Royal Melbourne Hospital, the University of Melbourne and the Murdoch Children's Research Institute.

"Epilepsy is one of the most prevalent and serious disorders of the central nervous system with an estimated prevalence of approximately 50 million cases worldwide, with 2.5 million cases in the US alone," Mr Jennings said.

"However carbamazepine and valproate, two first-line treatments for epilepsy, have limited efficacy, with 40 percent of patients having a significant adverse drug reaction and 20 to 40 percent experiencing recurring seizures," Mr Jennings said.

The easy to use diagnostic test has been validated in a large trial of more than 300 patients and is being trialed in a further 600 patients.

Influenza

Victorian scientists have developed an influenza vaccine that has the potential to increase the level of protection against common influenza and avian influenza.

Mr Jennings said researchers at Melbourne's Burnet Institute created the new formula using mannan, a carbohydrate found in plants and yeast, which added to the normal influenza vaccine, acts as an immune booster.

Mr Jennings said mannan had been administered to more than 200 humans in cancer vaccine trials and had proven to be safe.

"The scientists are about five years away from trialing the flu vaccine in humans," Mr Jennings said.

"If animal trials prove successful the 'flu vaccine could come onto the market within the next decade," he said.

BONE MEDICAL

Bone Medical has licenced the sale of Capthymone oral parathyroid hormone for osteoporosis in South Korea with Hyundai Pharm.

Bone said it would qualify for an undisclosed up-front payment, milestone payments related to product development, approval and launch events and payments for supply of bulk product.

Bone said it would receive royalties on annual sales of Capthymone by Hyundai Pharm.

Bone's managing director Troels Jordansen said it was "Bone's first heads of agreement for Capthymone".

"It is the kick-off for what we expect will be multiple licence agreements for Bone's technology that should enable rapid product sales when approvals are finalized," Mr Jordansen said.

"Our recent clinical development progress has shown Capthymone's effective [parathyroid hormone] oral delivery and we welcome the initiative demonstrated by our new partner Hyundai Pharm in negotiating rights to the product for its home market," Mr Jordansen said.

Mr Jordansen said Korean annual sales of osteoporosis products exceeded \$US100 million.

Bone Medical was up half a cent or 1.96 percent to 26 cents.

COGSTATE

Cogstate expects to record revenue growth of 50 percent this financial year following "a large increase in the number and value of sales contracts signed".

Cogstate says it has increased its customer base for its cognitive testing during the financial year, while continuing to service existing customers.

The company said contracts signed this financial year, especially in the second half of the financial year, would generate revenue for the next financial year and beyond.

Of the 36 sales contracts signed this financial year, 12 were for phase II studies and later stage studies typically generate more revenue than phase I studies, Cogstate said.

Chief executive officer Brad O'Connor said his company continued to have "significant demand for its cognition testing technology and associated services which has translated into contracts across the clinical trial spectrum".

Cogstate said it expected to report fourth quarter revenues and cash flows on July 25, 2008.

Cogstate was up half a cent or 4.76 percent to 11 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network's July 18 workshop examines intellectual property and due diligence.

The Network says companies need to consider the due diligence investigation of their intellectual property, prior to signing a deal or raising capital for the next phase of development.

"Have you carried out the necessary checks to be confident of your IP portfolio? What do you need to do to ensure that your investor gives you a 'tick'?" the Network asks.

Griffith Hack Patent and Trademark Attorney principals, Amanda Stark and Debbie Beadle, will discuss how your intellectual property will be examined in a due diligence investigation and ways in which you can strengthen your portfolio.

The Bio-Melbourne Network said they will consider the patent portfolio to protect your invention, claims to cover your lead compound or use, adequate fall back positions in case your broad claims are knocked out, filing in appropriate jurisdictions, adequate patent life, correct naming of all inventors, appropriate assignments from all inventors, joint inventors management, prior art that may invalidate your patent, freedom to operate and if there is a problem with your portfolio, what can you do about it?

Ms Stark and Ms Beadle have extensive experience as patent attorneys in Australia, the UK and Europe.

They have both been involved in due diligence many times, so they are alert to the problems which can arise, have experience in providing practical solutions and devising suitable patent strategies to ensure that the process runs as smoothly as possible.

Solubility director Lisa Keam will present on patent due diligence from an investor perspective and will examine key due diligence issues from both a pharmaceutical company and venture capital investment perspective and how to prepare for investor due diligence. Ms Keam has more than 15 years experience in intellectual property management and technology commercialization and was previously investment director at Starfish Ventures, a Melbourne based venture capital firm.

Registration will commence from 8:45am at Griffith Hack, Level 3, 509 St Kilda Road, Melbourne. The workshop will conclude at 12:30pm, followed by a light lunch.

The price for members of the Bio-Melbourne Network is \$350 per person and \$800 for non-members. For more information visit: www.biomelbourne.org or contact Nicole Pitcher on +613 9650 8800 or email: npitcher@biomelbourne.org.

ANADIS

Anadis has appointed Prof Colin Chapman and Simon Selimaj Sallka as non-executive directors with chief executive officer Dr Zeil Rosenberg appointed an executive director. Chairman Roman Zwolenski has resigned as chairman and as a director.

Anadis said a new chairman would be elected at the next board meeting, expected within the next few weeks.

Anadis said Prof Chapman was a former dean of the Faculty of Pharmacy at Monash University and continues as the Professor of Pharmacy where his work centres on drug development, immunology, dermatology and veterinary pharmacology.

The company said that during his period as dean of Pharmacy he played key roles in the commercialization of Relenza for influenza and in the establishment of Acrux, which is commercializing transdermal drug delivery developed in the Faculty of Pharmacy.

Anadis said Mr Sallka had more than 25 years experience in investment management and investment analysis and worked for extended periods in Japan, the US and Asia.

Anadis was unchanged at 5.2 cents.

OPTISCAN

Optiscan has appointed Dr Jim Fox and Paul Wright as directors.

Dr Fox will be join the board from July 1, 2008 and Mr Wright will join in late 2008.

Optiscan said Dr Fox had more than 27 years experience as a public company director with experience working with innovative, technology based companies in global markets.

In 2006 Dr Fox retired as the chief executive officer of Vision Systems following a takeover by a US company.

He is also a director of Air New Zealand, MS Research Australia, Futuris and TTP Group (UK).

Mr Wright has 10 years experience as chief executive officer of Invetech and Vision Biosystems, the major subsidiary of Vision Systems.

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