



Biotech Daily

Tuesday July 21, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: LIVING CELL UP 9%; ANTISENSE DOWN 13%**
- * **HEARTWARE STARTS EUROPEAN MINIATURE CARDIAC PUMP TRIAL**
- * **WEHI LINKS INFLAMMATION, ARTHRITIS, HEART VALVE DISEASE**
- * **PATRICK O'CONNOR REPLACES OPTISCAN CHAIR ANGUS HOLT
- GEORGE CAMERON-DOW DIRECTOR**
- * **BARCLAYS 'RETURNS' GENETIC TECHNOLOGIES SHARES BELOW 5%**
- * **REPRODUCTIVE HEALTH REQUESTS CAPITAL RAISING TRADING HALT**
- * **CELLMID APPOINTS PHARMAVENTURES DR FINTAN WALTON DIRECTOR**
- * **BIO-MELBOURNE AUGUST BREAKFAST ON EPILEPSY**
- * **INNOVATIONCAFE: PRODUCTIVITY, COMMERCIALIZATION, CULTURE**

MARKET REPORT

The Australian stock market was up 0.35 percent on Tuesday July 21, 2015 with the ASX200 up 19.8 points to 5,706.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and two were untraded.

Living Cell was the best, up 0.4 cents or 8.7 percent to five cents with 194,056 shares traded, followed by Cellmid up 8.6 percent to 3.8 cents with 2.6 million shares traded.

IDT and Osprey climbed more than seven percent; Universal Biosensors was up 6.7 percent; Circadian, Oncosil and Psivida were up more than four percent; Compumedics was up 3.45 percent; Anteo rose 2.6 percent; Actinogen, Admedus, Impedimed, Mesoblast and Sirtex were up more than one percent; with Cochlear, CSL and Medical Developments up by less than one percent.

Antisense led the falls, down 1.5 cents or 13.0 percent to 10 cents with 652,392 shares traded, followed by Genetic Technologies down 11.8 percent to three cents with 1.2 million shares traded and Analytica down 11.1 percent to 0.8 cents, with 2.1 million shares traded.

Prima lost 4.9 percent; Prana, Starpharma and Tissue Therapies fell more than three percent; Avita, Clinuvel and Nanosonics shed more than two percent; Acrux and Neuren lost more than one percent; with Resmed and Viralytics down less than one percent.

HEARTWARE INTERNATIONAL

Heartware says it has begun the 60-patient, Conformité Européenne (CE mark) clinical trial of its miniaturized ventricular assist device (MVAD) for heart failure.

Heartware said that the first patients receiving the pump were implanted at the Newcastle-upon-Tyne, England-based Freeman Hospital and at the Vienna, Austria General Hospital Medical University.

The company said that the MVAD weighed 78 grams, displaced 22 cubic centimetres of volume and supported a range of flows to enable circulatory support for patients with advanced heart failure.

Heartware said the pump was designed with a low shear stress impeller and optimal blood flow paths, which together were expected to result in improved hemodynamic performance.

The company said the pump had a steerable sewing ring, which enabled clinicians to position the inflow cannula to facilitate optimal blood flow into the pump.

Heartware said the integrated controller and battery system included a touch-screen display and two sizes of small, light-weight, snap-on batteries.

The company said that the CE mark trial, at 11 sites in the UK, Austria, Australia, France and Germany, was a prospective, non-randomized, single-arm trial evaluating the safety and performance of the MVAD system for advanced heart failure.

Heartware said that patients would be implanted with the pump through sternotomy or thoracotomy and the device would be evaluated for short- and long-term use.

The company said that the primary endpoint was survival at six months.

Heartware said it had submitted an investigational device exemption application to the US Food and Drug Administration for a US MVAD trial and Health Canada was reviewing a submission for a 15-patient study, expected to begin this year.

The company said that the MVAD system incorporated "a pulsatility algorithm called the Qpulse Cycle" that allowed physicians to customize the device for each patient, providing four pulse settings to enhance aortic valve function and reduce chronic bleeding events.

Heartware chief executive officer Doug Godshall said the "with the successful completion of these first implants in Europe, we are taking the next significant step in our efforts to help patients worldwide who suffer from advanced heart failure".

"The MVAD pump is less than half the size of our HVAD pump, currently the smallest commercialized full-support device, and is designed to be implanted through a less-invasive thoracotomy technique," Mr Godshall said.

Freeman Hospital investigator Prof Stephan Schueler said he was "encouraged by the initial implant and early post-operative experience with the MVAD system and believe that the benefits of this novel device have the potential to lead to better patient outcomes and an improved quality of life".

Vienna Hospital investigator Prof Daniel Zimpfer said that "since the MVAD pump requires a comparatively small thoracic space, it will be even more conducive to minimally invasive implant techniques, which is our preferred approach today with the current-generation HVAD pump".

"The MVAD device has the potential to reduce surgical trauma, enable use of fewer blood products during the procedure, decrease adverse events and lower post-implant hospitalization time," Prof Zimpfer said.

"Reducing the invasiveness of the surgery will not only enable us to treat a greater proportion of patients with heart failure but may offer a more attractive option to patients at an earlier stage of the disease progression," Prof Zimpfer said.

On the Nasdaq last night, Heartware was up \$US2.64 or 3.45 percent to \$US79.17 (\$A107.62 equivalent to \$3.075 per CDI prior to the company departing the ASX).

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it has identified a potential link between the excess production of inflammatory proteins and heart valve disease.

The Institute said that the research team discovered that a critical inflammatory protein involved in rheumatoid arthritis could also lead to inflammation and disease of the heart valves, including aneurysms.

WEHI said the research could lead to improved treatments for rheumatoid arthritis and suggested investigating existing medicines that dampened inflammation, to treat heart valve diseases, such as rheumatic heart disease.

The Institute said that Dr Philippe Bouillet, Dr Derek Lacey and colleagues identified critical regions of the DNA that controlled production of the inflammatory protein, tumour necrosis factor (TNF).

The research article, entitled 'Spontaneous retrotransposon insertion into TNF 3'UTR causes heart valve disease and chronic polyarthritis' was published online in the US Proceedings of the National Academy of Sciences and an abstract is available at:

<http://www.pnas.org/content/early/2015/07/17/1508399112.abstract>.

WEHI said that rheumatoid arthritis was a chronic inflammatory disease that affected two percent of the Australian population, causing debilitating joint pain and damage.

The Institute said that many people with rheumatoid arthritis produced too much TNF, which recruited immune cells that damaged joints and kept the body in a perpetual state of inflammation.

WEHI said that the link between TNF overproduction and the development of rheumatoid arthritis had been known for many years, but Dr Bouillet's team had identified new regions of the DNA critical for destabilizing the molecule.

"People with rheumatoid arthritis have too much TNF in their joints and in their blood," Dr Bouillet said.

"We have identified a previously unknown way that the body destabilises the molecules during the process of TNF production to stop too much of the protein being made," Dr Bouillet said.

"We could essentially develop agents that put a spanner in the works, stopping the factory production of TNF," Dr Bouillet said.

Dr Bouillet said that treating rheumatoid arthritis with drugs that reduced excess TNF had been very effective in managing the disease, but they had a downside.

"Up to 50 percent of patients become unresponsive to anti-TNF drugs because they develop immunity to this foreign protein," Dr Bouillet said.

"Targeting the regions of the DNA that destabilize the molecule could be an innovative way to interfere with protein production to dampen the amount of TNF being made," Dr Bouillet said.

"This is the first time that we have linked the overproduction of TNF to heart valve disease," Dr Bouillet said.

"While it seems that genetics makes a substantial difference to the severity of the heart disease in our models, it does suggest that in humans we may be able to better diagnose heart valve disease in people with rheumatoid arthritis in the future," Dr Bouillet said.

Dr Bouillet said that existing drugs that blocked and removed TNF could be investigated for treating heart valve diseases.

Dr Bouillet said that clinicians had trialled anti-TNF drugs for diseases of the heart muscle with poor results, but his group's studies suggested that excessive TNF drove heart valve, rather than heart muscle, diseases and might be worth investigating for inflammatory diseases affecting the heart valves, such as rheumatic heart disease.

OPTISCAN IMAGING

Optiscan says that executive chairman Angus Holt has resigned, with Patrick O'Connor appointed as chairman and George Cameron-Dow as a director.

Earlier this month, Optiscan responded to a lengthy and detailed ASX query regarding director's interest disclosures by Mr Holt (BD: Jul 10, 2015).

Optiscan said that Mr O'Connor would be a non-executive chairman and was an experienced company director

The company said that Mr O'Connor was currently a non-executive director of Stanmore Coal and was previously chairman of TFS Corp, Xceed Resources, Perilya, Water Corp and has been a non-executive director of a number of companies.

Optiscan said that Mr O'Connor held a Bachelor of Commerce from Stanford University in California.

The company said that Mr Cameron-Dow had board experience in industries including pharmaceutical, health care, funds management, automotive, packaging and building materials manufacturing, was currently a non-executive director of Bioxyne and Windward Resources and was previously the managing director of Xceed Capital, and a director of Calzada, now Polynovo)and Naracoota Resources.

The company said that Mr Cameron-Dow held a Master of Management from Stanford University.

Optiscan thanked Mr Holt for his efforts over the past six years, "steering the company through the challenging aftermath of the global financial crisis".

Mr Holt said that he became chairman in 2009, during the Global Financial Crisis, when the company had significant research and development ahead and required funding.

"I procured more than \$6 million in debt and equity to fund ... Optiscan's second generation imaging technology, the cornerstone of value creation," Mr Holt said.

"While Optiscan's technology has been in clinical use for nearly 10 years, the past six years has been largely about the development of the second generation imaging platform ... [which] produces real time, high definition, cellular images of a diagnostic quality," Mr Holt said.

Mr Holt said that the collaboration with Carl Zeiss for neurosurgery imaging was initially for the delineation of tumors during surgery, but the platform had "the potential to open a new and vast market of real time in-vivo pathology with enormous patient, doctor and health care system benefits" with potential applications in stomach, small bowel, liver, colon, ovaries, cervix, pleura, pancreas, bladder, prostate and cartilage.

Optiscan was unchanged at five cents with 1.4 million shares traded.

GENETIC TECHNOLOGIES

Barclays Bank says it has further reduced its substantial holding in Genetic Technologies from 87,949,121 shares (5.13%) to 82,519,121 shares (4.81%).

Last week, the London-based Barclays Bank said it had reduced its holding from 105,649,121 shares (6.16%) to 87,949,121 shares (5.13%) by returning 118,000 American depository receipts (ADRs) "borrowed" from an unnamed third party or third parties (BD: Jul 16, 2015).

Today the Bank said it had returned a further 36,200 ADRs.

Each Genetic Technologies ADR is equivalent to 150 Australian shares.

In April, Barclays Bank said it had become a substantial holder in Genetic Technologies with 122,877,121 shares, held for various custodians (BD: Apr 14, 2015).

Genetic Technologies fell 0.4 cents or 11.8 percent to three cents with 1.2 million shares traded.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health has requested a trading halt “pending an announcement to the market regarding a proposed capital raise”.

The company said the capital raise was for additional working capital to accelerate commercialization of its Embryocellect pre-implantation genetic screening service.

Trading will resume on July 23, 2015 or on an earlier announcement.

Reproductive Health last traded at 20 cents.

CELLMID

Cellmid says it has appointed the founder and chief executive officer of the Oxford-based Pharmaventures Dr Fintan Walton as a non-executive director.

Cellmid said that Dr Walton had more than 33 years experience in the pharmaceutical and biotechnology sector.

The company said Pharmaventures was a corporate advisory firm, assisting companies in corporate transactions, business brokering, mergers and acquisitions and licencing and since it was founded in 1992, it had advised clients in North America, Europe and Asia, delivering more than 700 assignments for 180 companies in 38 countries.

The company said that Dr Walton had worked with clients including most of the major and mid-sized pharmaceutical and biotechnology companies.

Cellmid said that Dr Walton held a Doctorate of Philosophy in genetics from Trinity College, Dublin.

Cellmid was up 0.3 cents or 8.6 percent to 3.8 cents with 2.6 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that its August 6, 2015 Bio-Breakfast will discuss diagnostic and treatment approaches to epilepsy.

The Bio-Melbourne Network said the breakfast, entitled ‘Innovation in Epilepsy at the Interface of Industry and Research’ would discuss new technologies, reimbursement, innovation in clinical trials, funding and investments, as well as industry, academic and clinical partnerships for research and development and commercialization.

The Network said that Australian Healthcare Solutions strategic director Matt Godden would lead a panel of experts in epileptic seizure detection, prediction and control who had experience working at the interface of industry and research.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that epilepsy was “a highly prevalent neurological disease” affecting more than 50 million people worldwide.

The Network said that the Bio-Breakfast panel included the Mountainview, California-based Neuropace chief medical officer Prof Martha Morrell, the Lyon, France-based Institut Des Epilepsies’ Prof Philippe Ryvlin and Portugal’s University of Coimbra Prof Antonio Dourado.

The Network said that novel forms of treatment approaches were being developed across a variety of industry sectors from pharmaceuticals, to bionic devices, through to brain monitoring systems, providing significant opportunities for growth.

The Bio-Melbourne Network said that a key problem in epilepsy was detection, prediction and control of seizures.

The August 6, 2015 Bio-Breakfast will be held at the Ian Potter Auditorium, Melbourne Brain Centre, Kenneth Myer Building, 30 Royal Parade, Parkville, with registration from 7.15am for breakfast with the panel discussion from 7.35am to finish 8.40am

To register go to: <http://www.biomelbourne.org/events/view/373>.

INNOVATIONCAFE

Tax advisers Swanson Reed with patent and trade mark attorneys Wrays are hosting a series of breakfasts on Australian productivity, commercialization and innovation culture. Through the vehicle of Innovationcafe, Swanson Reed and Wrays said the first of the two-hour events was held in Brisbane on July 1, 2015 with further sessions in Sydney on July 29, Perth on August 5 and Melbourne on August 12, 2015.

Innovationcafe said that the events would explore the importance of “the three pillars” of productivity, commercialization and innovation culture, with a panel of industry experts discussing the challenges and opportunities within each pillar for an innovative Australia, focusing on fields such as biotechnology and manufacturing.

The company said that the 7.30am to 10am workshops would “provide participants with the opportunity to develop solutions to the challenges discussed over breakfast and barista style coffee”.

The Sydney Innovationcafe on July 29 at the Sydney Hilton Hotel will hear from Health Industries SA chief executive Marco Baccanti, Merck Sharp and Dohme director Dr Phil Kearney and immunologist Prof Robert Clancy.

The Perth Innovationcafe on August 5, at the Hyatt Regency will host economic development advisor John Langoulant, Orbital Corp chief executive officer Terry Stinson and the University of Western Australia’s Prof Tim Mazzarol.

The final event will be in Melbourne on August 12 at the Melbourne Convention and Exhibition Centre with the University of Melbourne’s Prof Paul Jensen, Medical Developments chief executive officer John Sharman and Ausbiotech chief executive officer Dr Anna Lavelle.

The \$99 ticket price includes a buffet breakfast and coffee.

For more information and to book go to: www.innovationcafe.com.au.