



Biotech Daily

Wednesday October 14, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: NEUREN UP 11%; COMPUMEDICS DOWN 8%**
- * **RAMACIOTTI \$1.4m FOR BIOMEDICAL RESEARCH**
- * **CYNATA, MASSACHUSETTS GENERAL CANCER COLLABORATION**
- * **HEARTWARE FALLS 20% ON CE MVAD HALT**
- * **QUEENSLAND FUNDS HOSPITALS \$469k FOR SIMAVITA REHABILITATION**
- * **CYCLOPHARM DECLARES 0.5¢ MAIDEN INTERIM DIVIDEND**
- * **US PATENT FOR STARPHARMA VIVAGEL FOR BACTERIAL VAGINOSIS**
- * **US ALLOWS LBT APAS METHOD, SOFTWARE PATENT**
- * **BENITEC AGM FOR 6.7m DIRECTOR OPTIONS**
- * **ADMEDUS DIRECTOR IN LIEU SHARES, 10-TO-1 CONSOLIDATION AGM**
- * **ATCOR 3m DIRECTOR OPTIONS, ELECT RANDALL KING NELSON AGM**
- * **BIO-MELBOURNE TOURS TRAJAN SCIENTIFIC**

MARKET REPORT

The Australian stock market slipped 0.11 percent on Wednesday October 14, 2015, with the ASX200 down 5.6 points to 5,197.3 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and three were untraded.

Neuren was the best, up one cent or 11.1 percent to 10 cents, with 5.5 million shares traded. Actinogen climbed 9.1 percent; Atcor was up six percent; Genetic Technologies and Uscom were up more than five percent; Avita improved 4.35 percent; Acrux, Pro Medicus and Universal Biosensors were up more than three percent; Anteo, Circadian, Clinuvel, Orthocell, Resmed and Sirtex rose more than two percent; with Cochlear and Prima up more than one percent.

Compumedics led the falls, down three cents or 8.45 percent to 32.5 cents with 327,777 shares traded. Prana lost eight percent; Benitec and Bionomics fell more than five percent; Admedus shed 4.3 percent; Biotron, Oncosil, Polynovo and Starpharma were down more than three percent; Medical Developments, Osprey and Viralytics shed more than two percent; with Impedimed and Reva down more than one percent.

RAMACIOTTI FOUNDATIONS

The Ramaciotti Foundations have provided \$1,407,829 through its Biomedical Research Award, Medal for Excellence and Health Investment Grants.

A media release from Perpetual Trustees philanthropic division, which manages the Foundations said the \$1 million biennial Biomedical Research Award, went to the University of Queensland's Prof David Craik and La Trobe University's Prof Marilyn Anderson to help establish the Clive and Vera Ramaciotti Facility for producing pharmaceuticals in plants, for cheap medicines, potentially improving the lives of patients who could not afford current medications or could not tolerate the side effects.

Prof Craik said that the research had the "potential to provide medicines inexpensively to patients in both the developed and developing worlds ... however, this type of blue sky research falls outside the realm of work typically funded by government or industry so we are particularly grateful to the Ramaciotti Foundations for their support".

Perpetual said the Australian National University's Prof Carola Vinuesa won the \$50,000 Biomedical Research Medal for Excellence for her discovery of the Roquin family of proteins which opened avenues to diagnose and treat autoimmune diseases.

Perpetual said that four early career scientists would each receive up to \$150,000 in Health Investment Grants to support research with a potential path to clinical application within five years, including . the University of Newcastle, New South Wales Dr Nikola Bowden who received a grant for "repurposing traditional chemotherapy to prime advanced melanoma for immune therapy"; the University of Western Sydney's Dr Evelyn Smith to examine the relationship between obesity, inflammation and cognition within a randomized controlled trial of cognitive remediation therapy; Victoria's Bionics Institute of Australia's Dr Matt Petoe to improve patient performance with a second generation bionic eye; and Western Australia-based Edith Cowan University's Dr Elin Gray who won a grant to further study "circulating tumour DNA to predict and monitor treatment response and detect acquired resistance in patients with metastatic melanoma".

CYNATA THERAPEUTICS

Cynata says it has a collaboration with the Boston's Massachusetts General Hospital to develop modified mesenchymal stem cells to treat cancer.

Cynata said the collaboration, with the Hospital's director of the stem cell therapeutics and imaging program Dr Khalid Shah, would use its Cymerus platform technology.

The company said Dr Shah's team had reported "establishing a process to modify stem cells in the laboratory so that they secrete cancer-killing toxins ... [and had] a process to engineer the stem cells so that they themselves resist being killed by the toxins".

Cynata said that the research team was studying whether modified stem cells could deliver purified cancer-killing toxins directly to the site of a tumor to more effectively treat cancers while minimizing side effects.

The company said that Dr Shah's group would investigate similar modification of its Cymerus mesenchymal stem cells.

Dr Shah said he was "excited to work collaboratively with Cynata".

"Cynata's Cymerus technology is perfectly suited to the manufacturing requirements of cell-based therapies given the fact that it produces a consistent and reliable product, which we can manufacture economically at scale," Dr Shah said.

Cynata chief executive officer Dr Ross Macdonald said the program would be complementary to on-going commercial partnership discussions and the development of lead product CYP-001 continued to progress well.

Cynata climbed six cents or 14.3 percent to 48 cents.

HEARTWARE INTERNATIONAL

Heartware fell 20 percent on an update to the halt of its Conformité Européenne (CE) mark trial of its miniaturized ventricular assist device (MVAD) (BD: Jul 21, 2015).

Heartware said that it previously “disclosed on September 9, 2015, [that it had] paused its MVAD clinical trial to address an MVAD controller manufacturing process issue”.

On September 9, Heartware said that it provided updates to the Wells Fargo Healthcare Conference held in Boston, Massachusetts on several subjects, the last of which was “the progress of Heartware’s MVAD System CE mark international clinical trial, including a voluntary pause of trial enrolment to address assembly issues identified in the controller manufacturing process, which have not been seen in study devices and do not impact pump performance”.

Last night, Heartware told the SEC that it was “in the process of implementing manufacturing improvements as well as software updates, which were also described on September 9, 2015”.

“Subsequent to that action and following discussions with the company’s trial investigators, Heartware began investigating causes of reported adverse events in certain clinical trial patients,” the company said.

Heartware said that the events being analyzed were “typical of those seen in other clinical trials for ventricular assist devices”.

Heartware said that it took similar actions during its initial human study for its ventricular assist device system during its CE mark clinical trial in 2007.

“Although Heartware may not re-initiate enrolment in the MVAD clinical trial in November as it previously expected, Heartware remains confident in its MVAD System and the potential for the MVAD design to meaningfully improve outcomes for ventricular assist patients,” the company said.

Heartware said that remained the intention of the company to present and publish clinical data following the completion of enrolment and follow-up for all trial patients.

On the Nasdaq last night, Heartware fell \$US8.82 or 20.03 percent to \$US35.21 (\$A48.68, equivalent to \$A1.39 when it left the ASX) with 6,115,849 shares traded.

SIMAVITA

Simavita says the Queensland Government has provided a \$469,450, two-year contract for the supply of its smart incontinence management (SIM) at two hospitals.

Simavita said that the funding from the Queensland New Technology Funding and Evaluation Program was “the first of its kind in an acute care setting” and would supply its technology to the rehabilitation wards of two large Queensland public hospitals.

The company said that the use of SIM in this setting, as opposed to an aged-care facility, was “an outstanding new opportunity ... which could be repeated in additional hospital settings across Australia and potentially across other markets such as North America and Europe”.

Simavita said it was in the process of agreeing the deployment details with the hospitals.

Simavita chief executive officer Philippa Lewis said the hospitals had identified the SIM potential to assist patients undergoing rehabilitation and to shorten their hospital stays.

“We are delighted that the acute care market has recognised the benefits that SIM can deliver to patients and will continue to work with hospitals and rehabilitation facilities in Australia to further address this significant alternative market and the patient and cost benefits it can provide,” Ms Lewis said.

Simavita was unchanged at 43 cents.

CYCLOPHARM

Cyclopharm has recently declared a maiden interim dividend of 0.5 cents a share, fully franked, to be paid today.

Cyclopharm managing director James McBrayer said the dividend “strikes a balance between funding growth and providing for an increased dividend income to shareholders over time”.

“Our decision sends a fundamental message to investment markets that our financial future is sound and that our foreseeable growth aspirations are appropriately funded,” Mr McBrayer said.

Cyclopharm was up half a cent or 0.95 percent to 53 cents.

STARPHARMA HOLDINGS

Starpharma says the US Patent and Trademark Office has granted a patent for Vivagel “related to the prevention of recurrence of bacterial vaginosis”.

Starpharma said that the patent was entitled ‘Method of prophylaxis of bacterial vaginosis’ and had a term to 2032 providing an extension of seven years over granted Vivagel patents and an additional term might be available subject to timing of regulatory approval. The abstract for the patent on the USPTO website said that it covered the “methods of treatment or prophylaxis of bacterial vaginosis, prevention of recurrence of bacterial vaginosis and alleviation or prevention of symptoms or diagnostic criteria of bacterial vaginosis are provided”.

Starpharma said the patent built on its Vivagel patent portfolio that underpinned the Vivagel BV products.

The company said that the Vivagel patent portfolio comprised granted patents in key markets, including in Europe where the product had marketing approval for the topical treatment and relief of bacterial vaginosis, including symptomatic relief of vaginal odor and discharge.

Starpharma said that the market for the management of bacterial vaginosis and associated symptoms was estimated at more than \$US1 billion globally, with significant areas of unmet need, especially women with recurrent bacterial vaginosis.

The company said that Vivagel was “an effective treatment for the relief of [bacterial vaginosis] symptoms, ongoing use of Vivagel BV was shown in a phase II clinical study to reduce recurrence of [bacterial vaginosis] ... and a phase III clinical trial program for Vivagel BV for prevention of recurrent [bacterial vaginosis] was progressing well in North America, Europe and Asia”.

In 2013, Starpharma reported that a phase II trial of Vivagel for the prevention of recurrence of bacterial vaginosis failed to meet its primary endpoint with a “clinically” but not statistically significant difference between Vivagel and placebo (BD: Apr 3,4, 2013).

In 2012, Vivagel failed to meet its phase III trial primary endpoint for a clinical cure of bacterial vaginosis (BD: Nov 28, 29, 2012).

Today, Starpharma said that discussions on commercial rights for Vivagel BV were “underway with a number of potential partners”.

The company said that the patent grant would “extend the value of this product opportunity for both Starpharma and its partners”.

Starpharma chief executive Dr Jackie Fairley said the new patent was “confirmation of the innovation that Vivagel brings to the bacterial vaginosis field”.

“The patent is one of several in the Vivagel portfolio and further enhances the commercial value of Vivagel BV,” Dr Fairley said.

Starpharma fell three cents or 3.85 percent to 75 cents.

LBT INNOVATIONS

LBT said the US Patent and Trademark Office has allowed a second patent protecting the core software underpinning its automated plate assessment system.

LBT said the patent, entitled 'method and software for analysing microbial growth' provided coverage of the key systems and software for analysing and assessing microbial growth by the automated plate assessment system (APAS) until at least March 2032.

The company said the APAS prospects "were significantly bolstered" with results from a pivotal trial at Tricore Reference Laboratories, in which it achieved more than 98 percent sensitivity in its detection of bacteria in samples from 5,500 patients (BD: Oct 7, 2015).

LBT said the allowed application was part of a patent portfolio of four related inventions covering the APAS technology, for which LBT initiated patent protection early in 2011.

The first US patent, granted in March this year, related to a novel method for 'colour calibrating' images captured by APAS (BD: Mar 26, 2015).

LBT was up 3.5 cents or 28 percent to 16 cents.

BENITEC BIOPHARMA

Benitec will vote to grant five directors 6,720,000 options, ratify a prior issue of 10,000,000 options and re-elect director Kevin Buchi.

Benitec said that it proposed to issue 1,400,000 options to chairman Peter Francis, 2,800,000 options to chief executive officer Dr Peter French and 840,000 options each to directors Mr Buchi, Dr John Chiplotin and Iain Ross, all exercisable at 77 cents within five years from the date of issue.

The company said that the meeting would vote on the prior issue of 10,000,000 options exercisable at 27.5 US cents (38.0 Australian cents) each by August 21, 2020, "which were converted to Nasdaq listed warrants" along with the 10 percent placement capacity. The meeting will be held at Grant Thornton, Level 17, 383 Kent Street, Sydney, on November 12, 2015 at 10am (AEDT).

Benitec fell 2.5 cents or 5.3 percent to 44.5 cents.

ADMEDUS

Admedus will vote to issue directors \$227,766 worth of shares in lieu of fees, issue 2,000,000 director options and conduct a 10-for-one stock consolidation.

The Admedus notice of meeting said the company would issue \$90,046 in shares in lieu of director fees to chief executive officer Lee Rodne, \$54,120 in shares to director Michael Bennett, \$22,000 in shares to chairman Christopher Catlow, and \$15,400 in shares each to directors Wayne Paterson, Graeme Rowley, John Seaberg and Peter Turvey, all calculated at the 5-day volume-weighted average price to the date of issue.

The company said that shareholders would be asked to vote to issue 1,000,000 options each to Mr Seaberg and Mr Paterson, exercisable at 167 percent of the 5-day volume-weighted average price within five years of the date of issue.

Admedus said that it would seek shareholder approval for the prior issue of 171,500,000 placement shares at seven cents a share (BD: Mar 18, Apr 17, 2015).

The company said the meeting would vote on the approval of the 10 percent placement facility, employee option plan, deeds of indemnity access and insurance and re-elect directors Mr Turvey and Mr Bennett.

The meeting will be held at the Duxton Hotel, 1 St Georges Terrace, Perth, Western Australia on November 11, 2015 at 5pm (AWST).

Admedus fell 0.3 cents or 4.3 percent to 6.7 cents with 5.1 million shares traded.

ATCOR MEDICAL

Atcor will vote to grant chief executive officer Duncan Ross 1,000,000 options, 2,000,000 options to four directors and elect new director Randall King Nelson.

Atcor said that Peter Jenkins, who had been a director of the company for 16 years would retire at the annual general meeting and be replaced by Mr Nelson.

The company said that Mr Jenkins was originally a representative of venture capital firm Hambro Grantham, which provided initial funding and served as chairman for four years until 2003.

Atcor said that Mr Jenkins continued as an independent director having retired from Colonial First State Private Equity, which had acquired Hambro Grantham.

The company said that Mr King was based in California and had more than 30 years experience in the medical devices industry and was currently the chief executive officer of Uptake Medical Corp, a company focused on treatments for emphysema and lung cancer.

Atcor said that previously, Mr King was the chief executive officer of Kerberos Proximal Solutions, which was acquired by Foxhollow Technologies, and chief executive officer of Venpro, a heart valve business acquired by Medtronic.

Atcor said it proposed to grant 650,000 options to chairman Donal O'Dwyer, vesting in three tranches and exercisable at a 10 percent premium to the 5-day volume-weighted average price within five years, along with 450,000 options each to directors Dr Michael O'Rourke, Dr David Brookes and Mr Nelson director exercisable at a 15 percent premium to the 5-day volume-weighted average price within four years.

The company said it proposed to increase the pool for directors' fees by \$100,000 or 38.5 percent from \$260,000 to \$360,000.

Atcor said that shareholders would be asked to ratify the previous placement of 10,900,000 shares and 3,100,000 options (BD: Jun 17, Jul 22, 2015).

The company said the meeting would vote on the election of Mr O'Dwyer and Mr Nelson. The meeting will be held at Pricewaterhousecoopers, 201 Sussex Street, Sydney, on November 13, 2015 at 10am (AEDT).

Atcor climbed 1.5 cents or six percent to 26.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its October 20, 2015 Bio-Briefing will tour the Trajan Scientific and Medical facility in Ringwood.

The Network said that the tour and briefing would explore quality initiatives for manufacturing transformation and reducing errors through best practice training and hear from Seerpharma senior consultant and training manager David Spaulding and Trajan Scientific and Medical's general manager of glass technologies Steven van Winckel on quality, manufacturing and error reduction.

The Bio-Melbourne Network said that quality management was "essential for achieving business objectives" in biotechnology and medical technology.

The Network said the October 20, 2015 Bio-Briefing will be held at the Trajan Scientific and Medical, 7 Argent Place, Ringwood with registration from 3.45pm for the Bio-Briefing from 4pm to 5pm followed by a networking session.

To register go to: <http://www.biomelbourne.org/events/view/389>.