



Biotech Daily

Wednesday September 17, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ANALYTICA UP 12%, IDT DOWN 17%**
- * **WEHI TRIALS DENOSUMAB FOR BRCA MUTATION BREAST CANCER**
- * **FEDERAL MINISTER IAN MACFARLANE BACKS EYE RESEARCH, HOSPIRA**
- * **UNIVERSAL BIOSENSORS BLOOD COAGULATION TEST DELAYED**
- * **NANOSONICS TROPHON '3-FOLD MORE EFFECTIVE THAN WIPES'**
- * **HEALTHLINX APPOINTS TIMOTHY CHAPMAN DIRECTOR**
- * **MEDICINES AUSTRALIA APPOINTS LIBERAL STAFFER TIM JAMES CEO**
- * **ASIA UNION INCREASES, DILUTED TO 8% OF TISSUE THERAPIES**

MARKET REPORT

The Australian stock market fell 0.7 percent on Wednesday September 17, 2014 with the S&P ASX 200 down 38.1 points to 5,407.3 points.

Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and four were untraded. All three Big Caps fell.

Analytica was the best, on a general Pericoach intra-vaginal pelvic floor diagnostic marketing update, up 0.4 cents or 11.7 percent to 3.8 cents with 958,240 shares traded, followed by Admedus up 11.5 percent to 14.5 cents with 3.7 million shares traded.

Osprey and Prima climbed more than five percent; Acrux and Living Cell were up more than four percent; Tissue Therapies was up 3.5 percent; Benitec, Clinuvel and Sirtex rose more than two percent; with Nanosonics up 1.4 percent.

IDT led the falls, down four cents or 16.7 percent to 20 cents with 24,024 shares traded, followed by Universal Biosensors down 11.1 percent to 16 cents with 617,678 shares traded and Psivida down 10.2 percent to \$4.32 with 6,100 shares traded.

Phosphagenics lost 8.6 percent, Impedimed was down 6.7 percent; Prana was down 5.7 percent; Biotron and Patrys fell more than four percent; Antisense, Cellmid, Compumedics, Neuren and Oncosil were down more than three percent; GI Dynamics, Resmed and Viralytics shed more than one percent; with Alchemia, Cochlear, CSL and Mesoblast down less than one percent.

[THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH \(WEHI\)](#)

The Walter and Eliza Hall Institute says it is trialling denosumab as an alternative to mastectomy in women at high risk of BRCA-related breast cancer.

WEHI said that the clinical trial would test denosumab, which switched-off the cells that lead to breast cancer in people with BRCA mutations.

The Institute said that denosumab was used to treat osteoporosis and breast cancer that has spread to the bones, but had not been trialled for preventing breast cancer before.

WEHI said that Prof Geoff Lindeman, Prof Jane Visvader and Dr Sheau Wen Lok were leading the research at the Hall Institute and Royal Melbourne Hospital.

Prof Lindeman told Biotech Daily that the 30-patient study was a phase I, proof-of-principle trial which would examine safety and efficacy.

Prof Lindeman said that the trial would enroll 20 BRCA1 patients and 10 BRCA2 patients intending to have prophylactic mastectomies.

In a WEHI media release, Dr Lok said that up to 65 percent of women with mutations in the BRCA1 or BRCA2 genes would develop breast cancer in their lifetime and in Victoria, about one in five women with BRCA mutations would opt to have prophylactic mastectomy.

“Women with BRCA mutations can do a number of things to decrease their risk of developing breast cancer,” Dr Lok said.

“One effective option is to have prophylactic mastectomy, although this is a radical step for many women to take,” Dr Lok said.

Dr Lok said that current risk-reducing medication such as tamoxifen could cause significant side effects and although denosumab was not without potential side effects, it was generally well-tolerated and could present another option for women at high risk of BRCA-related breast cancers.”

WEHI said that Prof Visvader, Prof Lindeman and their team had previously shown that breast stem cell ‘daughters’, or progenitor cells, caused breast cancer in women with BRCA mutations.

The Institute said that In the BRCA-D study, breast tissue samples would be collected from women with BRCA mutations before and after administration of denosumab.

WEHI said that women in the trial would receive four doses of denosumab over the course of three months and have their breast tissue biopsied to look at the impact on cancer development.

The Institute said that denosumab was designed to inhibit the receptor activator of nuclear factor-B (RANK) protein ligand and in this study, it would be explored as a preventive medication to stop breast cancer developing in BRCA carriers.

Prof Lindeman said the team’s previous work had also shown that RANK ligand signalling pathways were responsible for instructing breast progenitor cells to grow and divide in response to female hormones.

“If we can block the growth of these progenitor cells, then we may be able to stop breast cancer growing,” Prof Lindeman said.

“This trial builds on many years of basic research at the Walter and Eliza Hall Institute, and we are very happy to see it move into clinical trials and on the path to making a tangible difference to women with breast cancer,” Prof Lindeman said.

WEHI said that The BRCA-D study would be in a collaboration with the Royal Melbourne Hospital, through the National Health and Medical Research Council-funded Centre for Translational Breast Cancer Research.

The Institute said that the research was made possible through tissue donated to the Kathleen Cuninghame Foundation Consortium for Research into Familial Breast Cancer and Victorian Cancer Biobank.

FEDERAL GOVERNMENT

Federal Industry Minister Ian Macfarlane has launched a robotic system to improve stem cell research for eye diseases at the Centre for Eye Research Australia.

An adviser to the Mr Macfarlane told Biotech Daily that the Swiss made robot would change the growth media for the pluripotent stem cells reducing the labor requirement in the research.

Mr Macfarlane said that medical technology and pharmaceuticals were two sectors where Australia could play to its strengths.

"This robotic system allows automation of a range of routine laboratory tasks and frees researchers' time to design projects and test hypotheses, meaning research findings move a lot more quickly," Mr Macfarlane said.

"The automated system can tirelessly maintain the stem cells required for the study of macular degeneration, glaucoma, and other eye diseases leading to vision loss," Mr Macfarlane said.

"This is a great example of industry, technology and research combining to improve outcomes in order to address real-world challenges, such as finding better treatments and a cure for blindness," Mr Macfarlane said.

"Australian industry must always look to innovate, collaborate and harness the latest science that will enable us to remain competitive in a tough global marketplace."

A media release from Mr Macfarlane's office said that the robot demonstration followed a visit to the Melbourne manufacturing site of pharmaceuticals supplier Hospira, which developed oncology and other cancer support drugs.

The media release said that Hospira had invested \$50 million in its local manufacturing capability in recent years, including a new filling line, employing 600 people and exporting 90 percent of their annual production to more than 70 countries, and employed 50 people in research and development.

"The Australian economy and Australian industry is going through a significant transition that will lead to new opportunities and new industries, so long as we make full use of our areas of strength to reach into global markets," Mr Macfarlane said.

"We must be smarter about the way we make things, we must focus on export led opportunities and growth, and we have to rely on science, innovation and technology to ensure our industries are knowledge intensive, adaptable, and attractive around the globe," Mr Macfarlane said.

UNIVERSAL BIOSENSORS

Universal Biosensors says that with partner Siemens Healthcare Diagnostics the launch of the point-of-care blood coagulation test has been delayed.

Universal Biosensors said that the launch of the prothrombin time international normalized ratio (PT-INR) testing system was due to take place in September 2014, but had been delayed "to allow for additional work to improve the manufacturing reliability of a sub-component of the hand-held analyzer".

Universal Biosensors said it was "working closely with Siemens with the aim of completing this final work before year end".

The company said that Siemens was working with it to develop and commercialize a range of novel coagulation testing systems that would deliver laboratory quality results at the point-of-care.

Universal Biosensors chief executive officer Paul Wright said that "taking a little more time to deliver a reliable, high quality product is critical for our joint success".

Universal Biosensors fell two cents or 11.1 percent to 16 cents.

NANOSONICS

Nanosonics says that a 240-sample study shows its Trophon EPR was significantly more effective than the standard manual wipe disinfection procedure.

Nanosonics said that compared to Trophon EPR automated ultrasound probe disinfection process, the manual method demonstrated a three-fold higher risk of cross contamination, which meant increased risk of infection for patients.

Nanosonics chief financial officer McGregor Grant told Biotech Daily that the study compared 120 samples collected from intracavity ultrasound transducer heads following disinfection quaternary ammonium compound wipes with 120 samples disinfected by the Trophon EPR.

Mr Grant said that bacterial plate counts showed a statistically significant difference in post-disinfection contamination levels ($p = 0.009$) with a three-fold increased risk of contamination when wipes were used compared with the Trophon EPR.

Mr Grant said that the study also assessed contamination rates on non-disinfected transducer handles and found that 83 percent were contaminated with bacteria.

In a media release, Nanosonics said that the study was carried out by the University Hospital Münster in Germany, with results presented at the World Congress of the International Society of Ultrasound in Gynecology and Obstetrics in Barcelona this week. University Hospital Münster head of prenatal medicine Dr Ralf Schmitz said that “thanks to Trophon EPR we can now offer our patients maximal infection protection during our ultrasound examinations”.

Nanosonics chief executive officer Michael Kavanagh said that effective reprocessing of ultrasound probes was essential for proper infection control.

“This European study further confirms the superior efficacy of the automated, validated disinfection delivered by Trophon EPR over current conventional manual practice,” Mr Kavanagh said.

“Despite the manual process being performed under strict study conditions, a three-fold higher risk of cross contamination was identified,” Mr Kavanagh said.

Nanosonics was up 1.5 cents or 1.4 percent to \$1.105.

HEALTHLINX

Healthlinx says it has appointed Timothy Chapman as a director.

Healthlinx said that Mr Chapman was a principal of Halcyon Corporate with more than 14 years experience in the financial services industry.

The company said that Mr Chapman had advised and worked on numerous capital raisings for public and private companies in the form of initial public offerings, reverse take-overs, private placements and right issues, as well as many merger and acquisition transactions.

Healthlinx said that Mr Chapman had raised capital for public and private companies in a number of industries including minerals and exploration, medical devices, media and entertainment, technology and infrastructure.

In June, Healthlinx said that it was pursuing a transaction which would change its activities from biotechnology to “a mobile video gaming” business.

Healthlinx said the transaction would be subject to relevant regulatory and shareholder approvals and a substantial capital raising (BD: Jun 13, 2014).

Healthlinx failed to commercialize its Ovplex test for ovarian cancer and last year went into administration emerging from administration this year (BD: May 7, 2013; Jan 31, 2014).

Healthlinx was untraded at 50 cents.

MEDICINES AUSTRALIA

Medicines Australia says it has appointed New South Wales Liberal Government political staff member Tim James as its chief executive from October 20, 2014.

Medicines Australia said that Mr James would replace Dr Brendan Shaw who finished in his role on September 12 to take up an appointment with the International Federation of Pharmaceutical Manufacturers & Associations in Geneva.

Medicines Australia chairman Dr Martin Cross said that Mr James had “a wealth of experience in government and policy, professional services as well as the medicines industry”.

Medicines Australia said that Mr James was currently the chief-of-staff to the New South Wales Minister for Resources and Energy and Special Minister of State Anthony Roberts. The industry organization said that previously Mr James worked in the pharmaceutical industry for several Medicines Australia member companies, as well as earlier being a lawyer and an auditor.

Medicines Australia said that Mr James previously worked for former Prime Minister John Howard and current Treasurer Joe Hockey.

Medicines Australia said that Mr James held a Masters of Business Administration from the Australian Graduate School of Management.

The organization said that Dr Cross would be the acting chief executive until October 20.

TISSUE THERAPIES

Asia Union Investments says it has increased in Tissue Therapies from 20,746,115 shares to 21,813,991 shares but has been diluted from 9.68 percent to 8.29 percent.

The Sydney-based Asia Union substantial shareholder notice said that between August 20, 2013 and September 15, 2014 it bought 7,275,706 shares for \$2,048,912 or an average price of 28.2 cents a share.

Last year, Tissue Therapies raised \$10 million in a placement and rights issue at 21 cents a share.

Tissue Therapies was up 1.5 cents or 3.5 percent to 44 cents.