

Biotech Daily

Tuesday June 17, 2014

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP: OSPREY UP 16%, USCOM DOWN 8%
- * WEHI GENE SWITCH REVERSES LEUKAEMIA
- * FDA CLEARS OSPREY 2nd GENERATION AVERT DYE REDUCTION SYSTEM
- * ATOMO POINT-OF-CARE DIAGNOSTIC WINS NEW YORK AWARD
- * RESONANCE RAISES \$1.3m OF HOPED-FOR \$5.1m
- * SUNSHINE HEART APPOINTS BRIAN BROWN HEAD OF OPERATIONS

MARKET REPORT

The Australian stock market fell 0.21 percent on Tuesday June 17, 2014 with the S&P ASX 200 down 11.6 points to 5,400.7 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and three were untraded.

Osprey was the best, up seven cents or 15.6 percent to 52 cents with 277,219 shares traded, followed by Acrux up 10 cents or 10.7 percent to \$1.035 with 4.9 million shares traded.

Analytica climbed 6.5 percent; Atcor and Universal Biosensors were up more than five percent; Biotron and Circadian were up more than four percent; Benitec was up 3.1 percent; Anteo, Genetic Technologies, Impedimed, Mesoblast and Sirtex rose more than two percent; Alchemia, Cochlear and Phosphagenics were up more than one percent; with GI Dynamics, Nanosonics and Resmed up by less than one percent.

Uscom led the falls, down two cents or 8.0 percent to 23 cents with 130,000 shares traded.

Prana lost 7.1 percent; Oncosil and Prima fell more than four percent; Admedus and Compumedics were down more than three percent; IDT and Neuren shed more than two percent; Bionomics and Starpharma were down more than one percent; with CSL down 0.3 percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that a common leukaemia can be reversed by coaxing the cancer cells back into normal development.

The Institute said that the discovery was made using a model of B-progenitor acute lymphoblastic leukaemia (B-ALL), the most common cancer affecting children.

WEHI said that its researchers led by Dr Ross Dickins and Grace Liu with collaborators in Vienna showed that switching off the paired-box-5 (Pax5) gene could cause cancer in a model of B-ALL, while restoring its function could cure the disease.

The study, entitled 'Pax5 loss imposes a reversible differentiation block in B-progenitor acute lymphoblastic leukaemia' was published in Genes & Development. An abstract was not available.

Ms Liu said the team used a newly-developed genetic switch technology to inhibit and then reactivate Pax5 in the leukaemia model.

"Along with other genetic changes, deactivating Pax5 drives normal blood cells to turn into leukaemia cells, which has been shown before," Ms Liu said. "However we showed for the first time that reactivating Pax5 enabled the cells to resume their normal development and lose their cancer-like qualities, effectively curing the leukaemia."

"What was intriguing for us was that simply restoring Pax5 was enough to normalise these cancer cells, despite the other genetic changes," Ms Liu said.

The Institute said that in leukaemia, immature white blood cells replicated abnormally and accumulated in the bone marrow, interfering with production of normal blood cells.

Ms Liu said Pax5 was a gene frequently lost in childhood B-progenitor acute lymphoblastic leukaemia.

"Pax5 is essential for normal development of a type of white blood cells called B cells," Ms Liu said. "When Pax5 function is compromised, developing B cells can get trapped in an immature state and become cancerous."

"We have shown that restoring Pax5 function, even in cells that have already become cancerous, removes this 'block', and enables the cells to develop into normal white blood cells," Ms Liu said.

Dr Dickins said the research shed light on the function of Pax5, which was one of about 100 genes known to suppress human tumors.

"When these tumor suppressor genes are inactivated by changes to the DNA, cancers start to develop," Dr Dickins said. "This work shows how inactivating the tumor suppressor gene Pax5 contributes to B-ALL development and how leukaemia cells become 'addicted' to low Pax5 levels to continue proliferating."

"Even though the B-ALL cells have multiple genetic mutations, simply reactivating Pax5 causes tumor cells to resume normal development and lose their cancerous properties," Dr Dickins said.

Dr Dickins said that forcing B-ALL cells to resume their normal development could provide a new strategy for treating leukaemia.

"While B-ALL has a relatively good prognosis compared with other cancers, current treatments can last years and have major side-effects," Dr Dickins said.

"By understanding how specific genetic changes drive B-ALL, it may be possible to develop more specific treatments that act faster with fewer side-effects," Dr Dickins said. "It is very difficult to develop drugs that restore the function of genes that are lost during cancer development," Dr Dickins said. "However by understanding the mechanisms by which Pax5 loss causes leukaemia, we can begin to look at ways of developing drugs that could have the same effect as restoring Pax5 function," Dr Dickins said.

He said that the genetic switch technology used to study Pax5 could also be used to understand tumor-suppressor genes in other cancers.

OSPREY MEDICAL

Osprey says the US Food and Drug Administration has granted 510(k) market clearance for its second generation Avert system for the controlled infusion of dye.

Osprey said it expected to begin sales in Texas "imminently" as a number of hospitals were routinely using the first generation system.

Osprey chief executive officer Mike McCormick said the company was "extremely pleased to achieve US clearance of our second generation Avert system".

"It is an excellent milestone for our company," Mr McCormick said.

"This system has a number of ease-of-use features that allow hospitals to use the Avert without the need for Osprey support staff at each case," Mr McCormick said.

"As a number of Texas hospitals have been routinely using the first generation system, we expect these easy to use features will drive broad adoption throughout Texas," Mr McCormick said.

"We are also currently enrolling patients at several sites for our randomized, multi-site post market [investigational device exemption] clinical trial for an expanded marketing claim of 'reduction of contrast-induced nephropathy'," Mr McCormick said.

"Our initial sales efforts in Texas is to successfully show the commercial potential, uptake and usage patterns of our Avert system in a single US State in preparation for a full US commercialization following FDA clearance of an expanded [contrast-induced nephropathy] reduction marketing claim which is expected in the second half of 2015," Mr McCormick said.

Osprey climbed seven cents or 15.6 percent to 52 cents.

ATOMO DIAGNOSTICS

The Sydney-based Atomo Diagnostics says its Atomorapid HIV test won the 'best in show' and 'in-vitro diagnostics' award at the Medical Design Excellence Awards in New York. Atomo chief executive officer John Kelly told Biotech Daily that the HIV test was launched in South Africa in January 2014 and its integration of lancing and precise blood collection gave the diagnostic better and more accurate usability at significantly cheaper cost than existing tests.

Mr Kelly said that the HIV test had 100 percent sensitivity or no false negatives, with greater than 99.6 percent specificity or less than .4 percent false positives.

Mr Kelly said that a test being developed for multiple types of malaria in Asia and Africa was demonstrating greater than 98 percent sensitivity and specificity and was being trialled in Burundi and Cambodia, with a launch planned for Southern Africa in August 2014.

He said that the diagnostic was designed to be easy to use for self testing, like existing pregnancy tests.

Mr Kelly said that his company was also developing the device to test for hepatitis C and allergies.

In a media release, Mr Kelly said that his daughter's successful battle with a childhood illness was the inspiration behind developing a rapid point-of-care or home-use blood test device.

Atomo said that the Atomorapid platform could accommodate test strips for a wide variety of conditions and delivered "better clinical outcomes for patients and health care providers by enabling simpler, safer and more accurate testing in the field or at home".

The company said it was "committed to getting the product launched in the US and Europe".

Atomo Diagnositics is a private company.

RESONANCE HEALTH

Resonance has raised \$1,277,000 of a hoped-for \$5.1 million in a placement and non-renounceable entitlement offer at five cents a share (BD: Apr 10, 2014)

Resonance said the placement of 10 million shares raised \$500,000 and the one-for-four entitlement offer raised \$777,000 from acceptances for 15,550,419 shares

Resonance said there was a shortfall of 77,197,422 shares worth \$3,859,871 and lead manager Azure Capital would assist in the placement of the shortfall.

Resonance said the funds would be used to further the development of its magnetic resonance imaging-based intellectual property including Hepafat-Scan, a liver fibrosis test and other products and general working capital.

Resonance fell 0.2 cents or 4.3 percent to 4.5 cents with 1.4 million shares traded.

SUNSHINE HEART

Sunshine Heart says it has appointed Brian Brown as operations and technology senior vice president to manage the C-Pulse aorta cuff research and development program. Sunshine Heart said that Mr Brown would be responsible for operations including internal and contracted manufacturing.

The company said that Mr Brown was formerly Boston Scientific's head of cardiovascular research and development for 10 years.

Sunshine Heart said that prior to joining Boston Scientific in 1994, Mr Brown held engineering and managerial roles at Scimed Life Systems.

The company said that Mr Brown held a Bachelor of Science in mechanical engineering from North Dakota State University.

Last night on the Nasdaq, Sunshine Heart was up 11 US cents or 1.92 percent to \$US5.83 (\$A6.23, equivalent to 3.1 cents before delisting from the ASX) with 29,980 shares traded (BD: Feb 15, 2012; Apr 29, 2013).