



Biotech Daily

Thursday March 19, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: ANALYTICA UP 39%, AVITA DOWN 7%**
- * **WEHI-345 SLOWS INFLAMMATION, MULTIPLE SCLEROSIS POTENTIAL**
- * **US APPROVAL FOR ANALYTICA'S PERICOACH**
- * **STC OFFERS \$140k FOR 5 MEDTECH ENTREPRENEURS WITH TALENT**
- * **JAPAN FAST TRACK INVESTMENT INCENTIVES FOR MESOBLAST**
- * **HUNTER HALL BUYS 1.3m SIRTEX SHARES TO 9.4%**
- * **HUNTER HALL TAKES 11% OF GI DYNAMICS**
- * **REPRODUCTIVE HEALTH RELEASES 17m ESCROW SHARES**
- * **OSPREY TAKES CAPITAL RAISING HALT TO SUSPENSION**
- * **DR BRONWYN EVANS APPOINTED TO FEDERAL GROWTH CENTRE**

MARKET REPORT

The Australian stock market climbed 1.86 percent on Thursday March 19, 2015 with the S&P ASX 200 up 108.5 points to 5,950.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and two were untraded.

Analytica was the best, up 0.7 cents or 38.9 percent to 2.5 cents with 8.85 million shares traded, followed by Phosphagenics recovering 18.2 percent to 3.9 cents with 14.1 million shares traded.

GI Dynamics climbed 7.7 percent; Nanosonics was up 6.4 percent; IDT and Living Cell rose more than five percent; Bionomics and Sirtex were up four percent or more; Impedimed was up 3.05 percent; Atcor, Mesoblast and Neuren rose more than two percent; Benitec, CSL and Ellex were up more than one percent; with Cochlear up 0.5 percent.

Avita the falls, down half a cent or 7.1 percent to 6.5 cents, with 83,743 shares traded. Pharmaxis retreated 6.7 percent; Genetic Technologies fell 5.6 percent; Compumedics and Optiscan fell more than four percent; Biotron, Prana, Tissue Therapies and Viralytics were down more than three percent; Starpharma shed 2.3 percent; Medical Developments, Oncosil and Universal Biosensors were down more than one percent; with Acrux, Psivida and Resmed down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it has developed a drug-like molecule that can halt inflammation and has shown promise in preventing the progression of multiple sclerosis. The Institute said that Dr Ueli Nachbur, Prof John Silke, Prof Guillaume Lessene, Prof Andrew Lew and colleagues developed the molecule, which inhibits a key signal that triggers inflammation.

WEHI said that multiple sclerosis was an inflammatory disease that damaged the central nervous system including the brain, spinal cord and optic nerves, with no cure and “a desperate need for new and better treatments”.

The Institute said that inflammatory diseases such as multiple sclerosis were triggered by an over-active immune system.

“Inflammation results when our immune cells release hormones called cytokines, which is a normal response to disease,” Dr Nachbur said.

“However when too many cytokines are produced, inflammation can get out-of-control and damage our own body, all of which are hallmarks of immune or inflammatory diseases,” Dr Nachbur said.

WEHI said that to slow the excessive immune response, its researchers developed a small drug-like molecule WEHI-345 that bound to and inhibited a key immune signaling protein called the receptor-interacting serine/threonine-protein kinase 2 (RIPK2), preventing the release of inflammatory cytokines.

Prof Lew said the team examined WEHI-345’s potential to treat immune diseases in mouse models of multiple sclerosis.

“We treated preclinical models with WEHI-345 after symptoms of [multiple sclerosis] first appeared, and found it could prevent further progression of the disease in 50 percent of cases,” Prof Lew said.

“These results are extremely important, as there are currently no good preventive treatments for [multiple sclerosis].”

The Institute said that the research, entitled ‘A RIPK2 inhibitor delays NOD signalling events yet prevents inflammatory cytokine production’ was published in the journal Nature Communications and an abstract was available at:

<http://www.nature.com/ncomms/2015/150317/ncomms7442/full/ncomms7442.html>.

WEHI said that Prof Lessene developed the molecule with colleagues in the Institute’s chemical biology division and said that WEHI-345 had potential as an anti-inflammatory agent.

“This molecule will be a great starting point for a drug-discovery program that may one day lead to new treatments for [multiple sclerosis] and other inflammatory diseases,” Prof Lessene said.

Dr Nachbur said institute scientists would use WEHI-345 to further investigate the signaling pathway that produced inflammatory cytokines and “to develop a better, stronger inhibitor of RIPK2 for treating inflammatory disease”.

“This signaling pathway must be finely balanced, because WEHI-345 only delayed signaling rather than blocked it,” Dr Nachbur said.

“Nevertheless, this delay is enough to completely shut off cytokine production,” Dr Nachbur said.

“Not only is this a potential new treatment, it is a great tool we can use to unravel this signaling pathway and identify other important proteins that control inflammation that could be a drug target,” Dr Nachbur said.

The Institute said the study was funded by the Australian National Health and Medical Research Council, the Swiss National Science Foundation, the Australian Research Council and the Victoria Government.

ANALYTICA

Analytica says that the US Food and Drug Administration has cleared its intra-vaginal Pericoch pelvic floor muscle diagnostic tool for sale.

Analytica said that the FDA had issued a substantial equivalence letter following the assessment of its 510(k) premarket notification submission for the Pericoach system which is used to strengthen pelvic floor muscles, primarily to treat incontinence.

The company said that the Pericoach system could to be marketed and sold in the US and its territories.

Analytica chief executive officer Geoff Daly said that “the rapid clearance is testament to the quality of the submission and the hard work and professionalism of Analytica’s product development and regulatory affairs team”.

“We can now pursue distribution agreements and enact our early adopter program,” Mr Daly said. “Combined with our [Conformité Européenne (CE) mark] we now have the regulatory foundation to sell the Pericoach globally.”

Analytica climbed 0.7 cents or 38.9 percent to 2.5 cents with 8.85 million shares traded.

SMALL TECHNOLOGIES CLUSTER, VICTORIA GOVERNMENT

Melbourne’s Small Technologies Cluster (STC) says the 2015 round of Medtech’s Got Talent will provide \$140,000 in service prizes to up to five medical technology concepts. The Cluster is an independent State Government-created technology hub and is supported by industry (BD: Nov 22, 2012).

STC said that applications for the second Medtech’s Got Talent had opened and the Victorian-wide challenge “focused on training and supporting emerging medical technology students, post-doctoral and recent graduate entrepreneurs”.

The Cluster said that last year’s winner was developing a minimally-invasive brain machine interface.

STC said that the program intended to assist entrepreneurs in pitching a product or business concept, developing a technology roadmap and launching commercialisation activities.

STC chief executive officer Dr Buzz Palmer said that the calibre of participants in last year’s round “was outstanding and we’re expecting great things from the 2015 intake”.

“Our 2013-‘14 grand prize winners, Smartstent, are already making big strides with their minimally-invasive brain-machine interface technology, which translates brain signals for use in the control of bionic limbs,” Dr Palmer said.

STC said that the 2015 round had opened, with early-bird applicants who lodged before March 30, able to receive in-depth feedback on their application, prior to the April 8, 2015 deadline.

The Cluster said that applicants needed to submit an executive summary by April 8 and the top 30 applicants would be invited to pitch at the April 16 “rapid fire round” and 16 semi-finalists would advance to the finals, which would select five finalists, who would each receive \$20,000 plus valuable service prizes and enter a six week, intensive accelerated technology road-mapping program.

STC said that the grand prize winner would be selected at a closed-door investor boardroom pitch on August 7 and receive an additional \$40,000.

The Cluster said that applications must be must be “championed” by a currently-enrolled student in a Victorian secondary college or university, a currently employed post-doctoral student in a Victorian university, research institute, hospital or company, or a recent graduate from any university and currently residing in Victoria.

For details go to: <http://www.stcaustralia.org/entrepreneur-challenge/>.

MESOBLAST

Mesoblast says the Japan External Trade Organization has provided fast track access to potential investment incentives across all levels of Government in Japan.

Mesoblast said that it was the only regenerative medicine company to receive the designation and would receive “a specially tailored market and Government incentive roadmap aimed at providing a more attractive business environment”.

The company said the Trade Organization reviewed “thousands of companies worldwide with the capacity to generate large-scale investment and employment in Japan through the establishment of Japanese hubs for research and development, manufacturing, and commercialization [and] 10 companies across all industries, including Mesoblast, were chosen to receive fast track access to specific incentives and programs”.

The Organization’s Oceania managing director, Shuichi Hirano, said the initiative was a result of the Japan revitalization strategy, created by the Government in 2013, that placed the activation of foreign direct investment as an important economic policy and set a goal of doubling the current investment balance to YEN35 trillion (\$A375.8 billion) in 2020.

“Japan is focused on becoming a dominant force in the regenerative medicine industry, which we believe holds great prospects to stimulate revenue and employment in Japan, as well as providing novel and cost-efficient solutions for patients with distinct, unmet medical needs,” Mr Hirano said.

Mesoblast chief executive Prof Silviu Itescu welcomed the recognition and said that Japan was “a major market for our cell-based therapeutics and offers near-term potential for product approvals and revenues”.

Japan, in conjunction with our current and future strategic partners,” Prof Itescu said.

Mesoblast was up nine cents or 2.3 percent to \$3.96 with 853,114 shares traded.

SIRTEX MEDICAL

Hunter Hall Investment Management has increased its substantial holding in Sirtex from 4,055,173 shares (7.17%) to 5,306,548 shares (9.39%).

Hunter Hall said that on March 17, 2015, when Sirtex announced that its Sirflox trial did not meet its primary endpoint and its shares fell 55 percent, Hunter Hall bought 1,251,375 shares for \$21,829,457 or \$17.44 a share, the first time Hunter Hall has bought Sirtex shares since May 2013 when it reached an internal maximum holding (BD: May 29, 2013). Hunter Hall has been a long term shareholder in Sirtex and in 2009 increased to 16,684,884 shares (29.92%) when the company was at \$2.35 a share and has sold shares at prices ranging up to \$34 a share (BD: Mar 5, 2009).

Sirtex was up 92 cents or 4.4 percent to \$21.87 with 1.6 million shares traded.

GI DYNAMICS

Hunter Hall Investment Management has increased its substantial shareholding in GI Dynamics from 45,536,619 shares (9.61%) to 52,693,955 shares (11.12%).

The Sydney-based Hunter Hall said it acquired 7,157,336 shares in three trades on March 16, 2015 for \$861,028 or 12.0 cents a share.

Earlier this month, GI Dynamics’ share price fell 50 percent following a US Food and Drug Administration halt to its pivotal trial its Endobarrier gastric liner for obesity and type 2 diabetes (BD: Mar 6, 2015).

Last year, Hunter Hall increased its holding in GI Dynamics following a share price fall of 19.6 percent on a European halt to its shipments of the Endobarrier (BD: Oct 7, 2014).

GI Dynamics was up one cent or 7.7 percent to 14 cents.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says it will release 17,120,193 shares from voluntary escrow on April 1, 2015.

Reproductive Health said that following the release from escrow the company would have 47,425,011 shares available for trading, with a further 3,885,154 shares in ASX escrow until April 17, 2016.

Reproductive Health was up one cent or 8.3 percent to 13 cents.

OSPREY MEDICAL

Osprey has requested a voluntary suspension to follow the trading halt requested on March 17, "pending an announcement by Osprey in relation to a proposed capital raising" (BD: Mar 17, 2015).

Osprey last traded at 58 cents.

FEDERAL GOVERNMENT

The Federal Government has appointed former Cochlear executive Dr Bronwyn Evans as the chair of the Medical Technologies and Pharmaceuticals Growth Centre

The Federal Minister for Industry and Science Ian Macfarlane said that all five Growth Centres would begin building new links between businesses and researchers to boost Australian industry's international competitiveness and enhance areas of competitive strength.

A media release from Mr Macfarlane's office said that the \$188.5 million Industry Growth Centres Initiative was "the cornerstone of the Australian Government's strategy to guide industry into a new era of growth, investment and jobs, by focusing on areas in which Australia has an edge over our competitors".

The media release said that the chairs of the centres would begin work with stakeholders in their industry sectors to develop a proposal for their respective centres, including consideration of locations.

The media release said that Dr Evans had been the chief executive officer of Standards Australia since October 2013 and previously was Cochlear's head of quality, clinical and regulation.

The Government said that from 2009 to 2012, Dr Evans was the chair of the Medical Technology Association of Australia and had extensive board experience.