



Biotech Daily

Wednesday June 26, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: AVITA UP 11%, GENETIC TECHNOLOGIES DOWN 8%**
- * **HOUSE OF REPRESENTATIVES PASSES IP AMENDMENT BILL**
- * **MESOBLAST READY FOR PHASE II DIABETIC NEPHROPATHY TRIAL**
- * **EVADO LAUNCHES CLINICAL TRIAL CLOUD APPLICATION**
- * **GI DYNAMICS APPOINTS AL-NOZHA MIDDLE EAST DISTRIBUTOR**
- * **FISHER FUNDS TAKES 7.45% OF UNIVERSAL BIOSENSORS**
- * **QRX REQUESTS 'FDA TALKS' TRADING HALT**

MARKET REPORT

The Australian stock market climbed for the first time in five trading days on Wednesday June 26, 2013 with the S&P ASX 200 up 75.7 points or 1.63 percent to 4,731.7 points.

Fifteen of the Biotech Daily Top 40 stocks were up, seven fell, 13 traded unchanged and five were untraded.

Avita was the best, up 1.5 cents or 11.1 percent to 15 cents with 2.5 million shares traded.

Acrux climbed 5.9 percent; Alchemia, Bionomics, Phosphagenics, Prana, Starpharma, Tissue Therapies and Viralytics were up more than four percent; Pharmaxis was up 3.6 percent; Allied Health and Osprey rose more than two percent; Psivida was up 1.5 percent; with Medical Developments and Sirtex up by less than one percent.

Genetic Technologies led the falls, down 0.8 cents or 8.2 percent to nine cents with 195,000 shares traded.

Benitec lost 6.7 percent; Neuren fell 5.5 percent; Optiscan was down 3.95 percent; Atcor and Resmed shed more than one percent; with Cochlear, Mesoblast and Nanosonics down by less than one percent.

FEDERAL GOVERNMENT

The Minister for Innovation Greg Combet says the Intellectual Property Laws Amendment Bill 2013 was passed by the House of Representatives today.

A Federal Government media release said the Bill struck “the right balance between encouraging innovation and ensuring the community has access to new technologies” and would improve Crown use provisions, protecting community access to new technology. “This Bill will clarify that the Government can intervene in circumstances such as where a patent would deny patients reasonable access to health care services, including gene-based cancer screening,” said Mr Combet.

The media release said that the Bill would implement the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property, which meant that Australian manufacturers could apply to the Federal Court for a compulsory licence to manufacture patented drugs for export to developing countries facing a health crisis.

The media release said the legislation provided for “a more streamlined business environment between Australia and New Zealand” more closely aligning the patent systems to enable a single patent attorney regime and single examination and application processes.

An officer of the Senate told Biotech Daily that the Bill was on the Senate notice paper but not yet on the program and said that “if the Government listed it on the program and the Senate supported it, the Bill could be passed late on Friday”.

MESOBLAST

Mesoblast says it has ethics approvals for a 30-patient phase II trial evaluating its adult mesenchymal precursor cells in patients with type 2 diabetes and diabetic nephropathy. Mesoblast said it received the Australian approvals for the two selected doses of a single intravenous infusion of its allogeneic or off-the-shelf mesenchymal precursor cells after safety data was reviewed from the ongoing 60-patient phase II trial evaluating mesenchymal precursor cells (MPCs) in people with early type 2 diabetes without diabetic nephropathy, or advanced kidney disease.

The company said that the randomized, placebo-controlled, dose-escalating phase II trial would evaluate the safety and efficacy of 150 million or 300 million intravenously-injected MPCs against placebo in 30 people with advanced diabetic nephropathy.

Mesoblast said that kidney function and protein loss, kidney blood flow, glucose control and markers of inflammation would be evaluated over 12 weeks.

The company said that diabetes was the leading cause of kidney failure, accounting for more than 40 percent of all cases of end stage kidney disease and that the US had 15 million cases of chronic kidney disease, with about 250,000 cases of stages 3b and 4 disease, the target patient population for MPC therapy.

Mesoblast said its preclinical studies in diabetic and non-diabetic animal models showed that MPCs reduced systemic inflammation, reversed vascular endothelial dysfunction, reversed abnormal kidney pathology and improved function via secretion of factors that enhanced regeneration and repair of kidney tissue.

Mesoblast said that along with glucose-lowering effects observed in mice and non-human primates with models of type 2 diabetes, the additional mechanisms of action suggest MPCs might benefit the principal complication of type 2 diabetes, diabetic nephropathy.

Mesoblast chief executive Prof Silviu Itescu said that the prognosis for patients with diabetic kidney disease was “grim [and] fewer than 50 percent of those with end stage kidney disease are alive five years after diagnosis”.

Mesoblast fell one cent or 0.18 percent to \$5.42 with 777,867 shares traded.

EVADO

The Melbourne-based Evado says it has launched “a breakthrough cloud application” named Uniform to streamline clinical trials”.

Evado said that the Uniform application would allow the management of information and complex data from a single page user-interface regardless of software, format or user device and would streamline business computing in all sectors, starting with clinical trials and healthcare.

Evado chief executive officer Jennie Anderson said that “until now ... business functions have been segmented into numerous [applications] that operate independently”.

“As a result, users must open multiple applications to complete a single business process or function and companies must upgrade apps on a regular basis,” Ms Anderson said.

“By standardizing user access across a wide variety of computer environments, Uniform allows users to access the same information, in the same format, regardless of whether they are using a smart phone, Ipad, android, desktop or laptop,” Ms Anderson said. “For example, medical staff will have the information they need to care for patients at their fingertips, in one application, no matter what device they are using and, they will be able to see patients' health information securely from anywhere, at any time, in any language.” Evado said that Uniform would be available by the end of 2013.

Evado is a private company.

GI DYNAMICS

GI Dynamics says the Jeddah, Saudi Arabia-based Al-Nozha Medical Est will distribute its Endobarrier for obesity and/or type 2 diabetes in three Middle East territories.

GI Dynamics said Al-Nozha had exclusive rights for Saudi Arabia, Qatar and the United Arab Emirates and the distribution agreement specified minimum purchases over a three-year period and was renewable based on Al-Nozha's achievement of certain milestones.

GI Dynamics chief commercial officer Mark Twyman said the Middle East was “an important self-pay market” and Al-Nozha's experience would be invaluable.

GI Dynamics was unchanged at 56 cents.

UNIVERSAL BIOSENSORS

New Zealand's Fisher Funds says it has increased its substantial shareholder in Universal Biosensors from 9,943,933 shares (6.25%) to 13,010,390 shares (7.45%).

Fisher Funds said that from September 4, 2012 to June 24, 2013 it acquired 3,066,457 shares for \$2,356,049 or an average price of 76.8 cents a share.

Universal Biosensors was unchanged at 67 cents.

QRX PHARMA

QRX has requested a trading halt pending an announcement “in relation to communications with the US Food and Drug Administration in relation to [its] new drug application for Moxduo”.

Trading will resume on June 28, 2013 or on an earlier announcement.

QRX last traded at \$1.12.