Biotech Daily

Monday June 16, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ADMEDUS UP 12%, ATCOR DOWN 7%**

*** GI DYNAMICS ENDOBARRIER: 'ACUTE DROP IN GLUCOSE, WEIGHT'**

*** MESOBLAST RECEIVES $5m FEDERAL R&D TAX REFUND**

*** GENERA: 'CANADA ROCHE APPROVAL BACKS PAPTYPE'**

*** USCOM APPOINTS UNETIXS VASCULAR USCOM 1A US DISTRIBUTOR**

*** LBT REQUESTS CAPITAL RAISING TRADING HALT**

*** INVION GRANTS CEO DR GREG COLLIER 10% PAY RISE TO $330k**

MARKET REPORT

The Australian stock market was up 0.13 percent on Monday June 16, 2014 with the S&P ASX 200 up 7.2 points to 5,412.3 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and five were untraded.

Admedus was the best, up 1.5 cents or 11.5 percent to 14.5 cents with 16.7 million shares traded.

Acrux and Prana climbed more than seven percent; Universal Biosensors was up 5.9 percent; Avita was up 4.55 percent; Antisense and Compumedics were up more than three percent; Genetic Technologies, Neuren and Prima rose more than two percent; Phosphagenics and Starpharma were up more than one percent; with Benitec and Cochlear up by less than one percent.

Atcor led the falls, down 0.7 cents or 7.0 percent to 9.3 cents with 489,781 shares traded.

Anteo and Bionomics lost five percent or more; Oncosil fell 4.35 percent; Impedimed shed 2.7 percent; Alchemia, Mesoblast, Nanosonics, Pharmaxis, Resmed, Sirtex and Tissue Therapies were down more than one percent; with CSL and GI Dynamics down by less than one percent.

GI DYNAMICS

GI Dynamics says a 33-patient Endobarrier study has shown an acute drop in average daily glucose within days of implant and significant weight loss within 12 weeks.

GI Dynamics said that the study, entitled 'The Acute Effect of Endobarrier Treatment on Glucose Homeostasis in Obese Uncontrolled Diabetic Subjects' evaluated the effects of the device on glucose homeostasis, blood glucose levels or HbA1c, weight loss, insulin requirements and appetite, with glucose monitored continuously for one week beginning two days before placement of the device.

The company said that the study found an average daily glucose reduction by 29 percent within days post-implantation, despite a reduction of 50 percent in insulin dose.

GI Dynamics said that the study found that as early as 12 weeks after Endobarrier insertion, subjects demonstrated a significant reduction in weight, with an average 8.9kg weight loss, as well as a 1.4 percent reduction in HbA1c levels leading to a decrease in insulin requirements.

The company did not provide the base line measurements for the weight loss or HbA1c reduction, but said that weight loss was accompanied by a decrease in appetite demonstrated by the visual analog scale.

GI Dynamics said a poster, entitled 'Endoscopic, Duodenal-Jejunal Bypass Liner Exerts Robust Improvement in Glycemia and Body Weight in Obese Patients with Type 2 Diabetes' reported on 71 patients who had completed 12 months of Endobarrier therapy.

The company said that the Endobarrier resulted in a 1.4 percent median decrease in HbA1c from 8.2 percent at baseline to 6.8 percent and 57 percent achieved the recommended 7.0 percent HbA1c of the American Diabetes Association.

The US National Institutes of Health website said non-diabetic levels were below 5.7 percent, pre-diabetic was 5.7 to 6.4 percent with diabetes diagnosed at 6.5 percent.

GI Dynamics said that average body weight fell 10.4 percent, from 106.2kg at baseline to 93.4kg and patients were able to reduce the use of background diabetes medications.

GI Dynamics said that research indicated that bile acids levels might be tied to the effectiveness of gastric bypass surgery, such as Roux-en-Y gastric bypass and a third seven-patient study, entitled 'Duodenal-Jejunal Bypass Liner Increases Bile Acids Levels in Patients with Severe Obesity and Type 2 Diabetes Mellitus' investigated the effect of the Endobarrier on bile acids.

GI Dynamics said that primary and secondary bile acids levels were measured prior to placement of the Endobarrier and following removal at 52 weeks of treatment.

The company said that after treatment, fasting total bile acids levels increased to 4.3 ± 0.8 micro-mol/L, from 0.7 ± 0.3 micro-mol/L at baseline ($p < 0.05$).

GI Dynamics said that fasting primary bile acid levels increased from 0.04 ± 0.01 to 2.1 ± 0.4 micro-mol/L and secondary bile acids levels from 0.07 ± 0.02 to 1.5 ± 0.4 micro-mol/L increased from baseline ($p < 0.05$ compared to baseline for both).

GI Dynamics did not explain the relevance of increased bile acid levels.

The company said that the most common complications were nausea, vomiting and upper abdominal pain, with other uncommon risks including infection, trauma, device migration and bleeding, any of which may result in endoscopic or surgical removal.

GI Dynamics chief medical officer Dr David Maggs said that the data presented at the American Diabetes Association meeting expanded on the "already established evidence presented recently at other medical meetings and further validate how the Endobarrier device works to affect and improve glycaemic control".

"The findings from these studies and analyses show that Endobarrier positively impacts HbA1c and weight in patients with type 2 diabetes and obesity," Dr Maggs said.

GI Dynamics fell half a cent or 0.9 percent to 57.5 cents.

MESOBLAST

Mesoblast says it has received $5.05 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Mesoblast said the rebate related to research and development expenditure for the year to June 30, 2013 and it expected to receive further reimbursement of funds used for pipeline development in the year to June 30, 2014.
Mesoblast fell seven cents or 1.6 percent to $4.33 with 367,740 shares traded.

GENERA BIOSYSTEMS

Genera says that Health Canada's approval of the Roche Cobas 4800 human papillomavirus test is part of a global trend as the primary screen for cervical cancer.
Genera said that the US Food and Drug Administration approved the Roche competitor product as the first human papillomavirus test DNA test for women 25 and older that could be used alone to help a health care professional assess the need for a woman to undergo additional diagnostic testing for cervical cancer (BD: Mar 18, 2014).
The company said that Roche's Cobas 4800 test provides both pooled high-risk human papillomavirus DNA results and individual detection of human papillomavirus 16 and human papillomavirus 18, the two types responsible for about 70 percent of cervical cancer.
Genera said that Health Canada's decision to approve the expanded use for the Cobas test was based on results from a landmark trial, which enrolled more than 47,000 women and demonstrated that one in four women who were human papillomavirus (HPV) 16 positive would have cervical disease within three years and that nearly one in seven women with normal Pap cytology who were HPV 16 positive actually had high-grade cervical disease that was missed by cytology.
The company said the ability of the Roche test to simultaneously genotype HPV 16 and HPV 18 was a key determinant in Health Canada's primary screening approval decision.
Genera said that its Paptype HPV test simultaneously genotyped high risk HPV types but went further by genotyping 14 high risk types.
The company said that HPV types 16 and 18 accounted for about 70 percent of cervical cancer cases but the incorporation of simultaneously genotyping of 14 high risk HPV types, which caused 99.7 percent of cases, had the potential to substantially increase specificity of an HPV test, particularly when used within a long-term screening program.
Genera said that with the support of the New Mexico HPV Pap Registry it planned to generate additional clinical data for its Paptype HPV test in a 60,000 patient screening population and the Paptype would be assessed in a clinical screening study of 6,000 patients by the London-based Wolfson Institute of Preventative Medicine to confirm the potential superior specificity of its test compared to the Roche Cobas test and others.
Genera executive chairman Lou Panaccio said that Roche's submission for a screening approval of its cobas HPV test "accords with the view formed by Genera many years ago which led to the development of our Paptype HPV test and its protection through a robust portfolio of patents, many of which have been granted in the past few years with coverage extending to 2025 and beyond".
Mr Panaccio said that a previous study of samples run at the Wolfson Institute showed that the Paptype test had comparable sensitivity to all other commercially available HPV tests, including the Roche Cobas HPV test, but was the only test capable of simultaneously genotyping 14 high risk types delivering higher specificity.
Genera said that the global HPV testing market was worth about $US2 billion a year.
Genera was up seven cents or 25.9 percent to 34 cents.

USCOM

Uscom says it has appointed the Rhode Island-based Unetixs Vascular Inc as a non-exclusive distributor of the Uscom 1A ultra-sonic cardiac output monitor for three years.
Uscom said that Unetixs Vascular was wholly-owned subsidiary of Opto Circuits (India) and was a manufacturer and distributor of vascular monitoring equipment.
Uscom was untraded at 25 cents.

LBT INNOVATIONS

LBT has requested a trading halt “pending the announcement “in relation to a potential capital raising”.
Trading will resume on June 18, 2014 or on an earlier announcement.
LBT last traded at 16 cents.

INVION

Invion says that chief executive officer Dr Greg Collier has had a 10 percent basic pay rise from $300,000 to $330,000.
Invion said the pay rise followed an annual remuneration review and was effective from May 6, 2014, which was 12 months after Dr Collier’s appointment.
The company said that all other terms of Dr Collier’s appointment and remuneration remained unchanged.
Invion fell 0.3 cents or 4.4 percent to 6.5 cents with 1.4 million shares traded.