Biotech Daily

Thursday May 12, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 12.5%, ONCOSIL DOWN 7%**

*** FEDERAL GOVERNMENT CALL FOR SUBMISSIONS ON $20b MRFF**

*** EUROPE CONFIRMS CSL'S IDELVION FOR HAEMOPHILIA B**

*** ANTISENSE FDA ORPHAN STATUS FOR ATL1103 FOR ACROMEGALY**

*** SCOTT SCHORER TO 'REBOOT' GI DYNAMICS**

*** CREDIT SUISSE, JP MORGAN CHASE MESOBLAST SUBSTANTIAL NOTICES**

MARKET REPORT

The Australian stock market fell 0.24 percent on Thursday May 12, 2016 with the ASX200 down 13.0 points to 5,359.3 points.

Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and three were untraded.

Antisense was the best for the third day in a row, up 0.6 cents or 12.5 percent to 5.4 cents with 1.2 million shares traded, followed by Living Cell up 10 percent to 5.5 cents with 181,000 shares traded.

Benitec climbed 9.1 percent; Actinogen was up 6.8 percent; Compumedics and Opthea were up more than five percent; Reva was up 3.7 percent; Airxpanders, Anteo and Pharmaxis rose two percent or more; with CSL, Resmed and Starpharma up by less than one percent.

Oncosil led the falls, down one cent or 7.1 percent to 13 cents with 1.1 million shares traded.

Admedus and Neuren lost more than five percent; Bionomics, Cochlear, Impedimed and Prana fell more than four percent; Mesoblast and Polynovo were down more than three percent; Nanosonics, Orthocell and Prima shed more than two percent; Clinuvel, Medical Developments, Osprey and Universal Biosensors were down more than one percent; with Ellex, Pro Medicus and Sirtex down by less than one percent.

FEDERAL GOVERNMENT, MEDICAL RESEARCH FUTURE FUND

The Federal Government has called for submissions on the medical research and innovation strategy and priorities for the $20 billion Medical Research Future Fund.
A Department of Health media release said the Fund's research advisory board had held its first meeting and agreed to a two-stage consultation process to inform the development of the Australian Medical Research and Innovation Strategy and related Priorities.
In April, the Federal Government said the board would be chaired by the Prof Ian Frazer, with members including the University of Queensland's Prof Peter Høj, Walter and Eliza Hall Institute director Prof Doug Hilton, Medical Device Research Institute director Prof Karen Reynolds, Bionomics chief executive officer Dr Deborah Rathjen, Australian Private Equity and Venture Capital Association's Yasser El-Ansary, former Red Cross Blood Service chief executive Jennifer Williams and NHMRC executive officer Prof Anne Kelso.
The media release said that the Strategy would be determined every five years and the Priorities every two years.
The Government said that the first stage calling for public submissions would close on June 6, 2016 and the second stage would follow in July with targeted consultations.
The media release said that a consultation paper incorporating the building blocks for the Strategy and a pro forma for articulating priorities, together with instructions for making a written submission was on the Department of Health consultation hub at https://consultations.health.gov.au/research-data-and-evaluation-division/mrff.
All queries can be directed to MRFF@health.gov.au.

CSL

CSL says the European Commission has approved Idelvion for the treatment and prophylaxis of bleeding in adults and children with haemophilia B.
In February, CSL said that the European Committee for Medicinal Products for Human Use had recommended marketing authorization of Idelvion, a long-acting albumin fusion protein-linking recombinant coagulation factor IX with recombinant albumin, for haemophilia B, or congenital factor IX deficiency (BD: Feb 29, 2016).
In March, the company said that the US Food and Drug Administration had approved Idelvion, formerly CSL654, for haemophilia B (BD: Mar 7, 2016).
Today, CSL said that the European-approved treatment regimen included routine prophylaxis to prevent or reduce the frequency of bleeding episodes, on-demand control and the perioperative management of bleeding, near the time of surgery.
The company said that Idelvion delivered "high-level protection maintaining factor IX activity levels above five percent in most patients over 14 days" so that appropriate patients, aged 12 years and older could take up to 14 days between infusions and achieve bleeding control, which reduced the monthly number of units needed for prophylaxis.
CSL chief scientific officer Dr Andrew Cuthbertson said that Idelvion "provides excellent bleeding control by maintaining factor IX activity levels above five percent over a prolonged period of time".
"Idelvion delivers on CSL's 100-year promise to develop and provide innovative specialty biotherapies that patients need and want," Dr Cuthbertson said.
"We look forward to bringing Idelvion to the European market and are particularly excited about the positive impact this long-acting therapy can have on the lives of patients with haemophilia B as we enter our next century," Dr Cuthbertson said.
CSL said that Idelvion was available in the US and Canada and would be launched in Europe in the coming months, as market access and pricing were obtained.
CSL was up 56 cents or 0.5 percent to $110.58 with 769,531 shares traded.

ANTISENSE THERAPEUTICS

Antisense says the US Food and Drug Administration has granted orphan drug designation to ATL1103 for Acromegaly.

Antisense said that ATL1103 was designed to block growth hormone receptor expression in advanced clinical development and was a potential treatment for diseases associated with excessive growth hormone action including acromegaly.

The company said that orphan designation was granted by the FDA to drugs intended for the safe and effective treatment of rare diseases that affect fewer than 200,000 people in the US.

Antisense said that the FDA provided incentives for companies to develop products for rare diseases which may include tax credits towards the cost of clinical trials, waiver of US prescription drug filing fees and seven year orphan product exclusivity on marketing authorization.

The company said that the exclusivity meant that orphan drugs generally had a premium on their commercial value.

Antisense said it had begun the process of applying for orphan drug designation for ATL1103 in acromegaly to the European Medicines Agency, where the designation qualified the sponsor for 10 years of marketing exclusivity.

Antisense managing-director Mark Diamond said the US designation was “an important regulatory and commercial milestone in the further development of ATL1103 and represents another key step forward towards bringing this potentially transformative therapy to patients with a significant unmet need”.

Antisense was up 0.6 cents or 12.5 percent to 5.4 cents with 1.2 million shares traded.

GI DYNAMICS

GI Dynamics chief executive officer Scott Schorer says he intends to “reboot” the company following the closing of its 500-patient pivotal US Endobarrier trial.

The trial was halted by the US Food and Drug Administration following a higher than expected level of liver abscesses apparently caused by a combination of the hooks anchoring the Endobarrier to the duodenum and a high dose of proton pump inhibitors intended to reduce stomach acid (BD: Jul 30, 31, 2015).

In March, GI Dynamics said that the statistical power of the smaller than expected sample size of 325 enrolled patients resulted in the Endobarrier failing to meet its primary safety and efficacy endpoints (BD: Mar 15, 2016).

Today, Mr Schorer told a teleconference that the company had a new management team and the trial evidence was “encouraging”.

Mr Schorer said that the company knew it was in a difficult situation, but he believed Endobarrier was safe and effective and could provide a treatment for patients with obesity and type 2 diabetes.

Mr Schorer said that he had hired Brian Callahan for regulatory issues and “he will treat regulatory employees with respect and dignity and repair relations in all three regions”.

Mr Schorer said it was important for GI Dynamics to engage with investors directly and he would come to Australia in the next fortnight.

GI Dynamics was untraded at 1.7 cents.

MESOBLAST

Credit Suisse and JP Morgan Chase have filed a series of substantial shareholder notices in Mesoblast saying that they each hold about 40 percent of the company.

The two institutions were involved in last year's $95.8 million capital raising to list on the Nasdaq, and hold shares owned by Mesoblast directors prior to and through the capital raising in "lock-up" (BD Nov 5, 16, 17, 19, 20, 2015).

The holdings overlap and include large shareholders such as Cephalon (now Teva) with 55,785,806 shares, as well as 67,756,838 shares held by chief executive Prof Silviu Itescu and 1,059,000 shares held by director Michael Spooner.

The Credit Suisse statement said that chairman Brian Jamieson held 335,000 shares and "Brians Maserati Pty Ltd" held 275,000 shares (BD: Nov 5, 2015).

The substantial shareholder notices said that directors William Burns held 26,667 shares, Donal O'Dwyer held 300,000 shares, Dr Ben-Zion Weiner held 26,667 shares, Dr Eric Rose held 26,667 shares and chief financial officer Paul Hodgkinson held 150,000 shares.

A Mesoblast US Securities and Exchange Commission filing said that Josaka Investments, which held 487,804 shares, was a company associated with Prof Itescu and the Mr O'Dwyer related entities, Dundrum Investments Dundrum Superannuation Fund, held 292,903 shares and 511,824 shares, respectively.

According to Credit Suisse and JP Morgan Chase the balance is held on behalf of other unnamed clients who buy, sell, lend and borrow Mesoblast shares.

On November 4, 2015 Credit Suisse Holdings Australia said it became substantial with 131,856,954 shares or 35.61 percent.

On November 5, 2015 JP Morgan said it became substantial with 127,703,105 shares or 34.49 percent.

On May 9, 2016, JP Morgan said it held 128,563,297 shares or 33.71 percent.

Today, Credit Suisse said it held 133,228,730 shares or 34.93 percent.

Mesoblast fell 7.5 cents or 3.9 percent to $1.865 with 1.1 million shares traded.